

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

THE JUDGE ROTENBERG
EDUCATIONAL CENTER, INC.,

Petitioner,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,
STEPHEN M. HAHN, M.D., in his official
capacity as COMMISSIONER OF
FOOD AND DRUGS,

and

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, ALEX M. AZAR, II,
in his official capacity as SECRETARY OF
HEALTH AND HUMAN SERVICES,

Respondents.

No. 20-1087

PETITION FOR REVIEW

Pursuant to 21 U.S.C. § 360g(a)(5), 5 U.S.C. § 704, 21 C.F.R. §§ 10.45(d) and 895.21(g), Federal Rule of Appellate Procedure 15(a), and District of Columbia Circuit Rule 15, Petitioner The Judge Rotenberg Educational Center, Inc. hereby petitions this Court to review and set aside a final regulation issued by the U.S. Food and Drug Administration banning electrical stimulation devices used to treat aggressive or self-injurious behavior, dated March 6, 2020, and published in the

Federal Register on March 6, 2020 at 85 Fed. Reg. 13312 (the “Final Rule”), a copy of which is attached hereto as **EXHIBIT A**.

Petitioner seeks judicial review on the grounds that the Final Rule, *inter alia*, is contrary to law, clearly erroneous, arbitrary and capricious, an abuse of discretion, and unsupported by substantial evidence on the record taken as whole as required by 21 U.S.C. §360g(c), and in violation of Due Process and Equal Protection of the law as guaranteed by the Fifth Amendment to the United States Constitution. Petitioner respectfully requests that this Court hold unlawful, vacate, enjoin, set aside and/or remand the Final Rule, and grant Petitioner such other and further relief as may be deemed just and proper.

Jurisdiction and venue are proper in this Court pursuant to 21 U.S.C. §§ 360g(a) and (c).

Respectfully submitted,

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Dated: March 26, 2020 *Attorneys for Petitioner*

Exhibit A



13312

Federal Register / Vol. 85, No. 45 / Friday, March 6, 2020 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 895

[Docket No. FDA-2016-N-1111]

Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is finalizing a ban on electrical stimulation devices (ESDs) for self-injurious or aggressive behavior. FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. This ban includes both new devices and devices already in distribution and use; however, this ban provides transition time for those individuals currently subject to ESDs for the identified intended use to transition off ESDs under the supervision of a physician.

DATES: This rule is effective April 6, 2020. However, compliance for devices currently in use and subject to a physician-directed transition plan is required on September 2, 2020. Compliance for all other devices is required on April 6, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov/> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring MD 20993-0002, 301-796-6527, rebecca.nipper@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose of the Final Rule
 - B. Summary of the Major Provisions of the Final Rule
 - C. Legal Authority
 - D. Costs and Benefits
- II. Table of Abbreviations and Acronyms
- III. Background and Determination
 - A. Public Participation, Clarifications, and Key Changes

- B. FDA's Determination That ESDs for SIB or AB Present an Unreasonable and Substantial Risk of Illness or Injury
- IV. Legal Authority
- V. Comments on the Proposed Rule and FDA's Responses
 - A. Background Information About ESDs, SIB, and AB
 - B. Evidence Interpretation
 - C. Risks of ESDs for SIB or AB
 - D. Effects of ESDs on SIB and AB
 - E. State of the Art for the Treatment of SIB and AB
 - F. Labeling and Correcting or Eliminating Risks
 - G. Legal Issues
 - H. Transition Time
- VI. Effective Date and Compliance Dates
- VII. Economic Analysis of Impacts
- VIII. Analysis of Environmental Impact
- IX. Paperwork Reduction Act of 1995
- X. Federalism
- XI. References

I. Executive Summary

A. Purpose of the Final Rule

FDA is banning ESDs for self-injurious behavior (SIB) or aggressive behavior (AB). ESDs are aversive conditioning devices that apply a noxious electrical stimulus (a shock) to a person's skin to reduce or cease such behaviors. SIB and AB frequently manifest in the same individual, and people with intellectual or developmental disabilities exhibit these behaviors at disproportionately high rates. Notably, many such people have difficulty communicating and cannot make their own treatment decisions because of such disabilities, meaning many people who exhibit SIB or AB are part of a vulnerable population. SIB commonly includes head-banging, hand-biting, excessive scratching, and picking of the skin. However, SIB can be more extreme and result in: (1) Bleeding; (2) broken, even protruding bones; (3) blindness from eye-gouging or poking; (4) other permanent tissue damage; or (5) injuries from swallowing dangerous objects or substances. AB involves repeated physical assaults and can be a danger to the individual, others, or property. In this rule, like much of the scientific literature, we discuss SIB and AB in tandem and use the phrase "SIB or AB" to refer to SIB or AB or both.

Although the available data and information show that some individuals subject to ESDs exhibit an immediate interruption of the targeted behavior, the available evidence has not established a durable long-term conditioning effect or an overall-favorable benefit-risk profile for the devices. The medical literature shows that ESDs present risks of a number of psychological harms including depression, posttraumatic stress

disorder (PTSD), anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage.

Because the medical literature likely underreports adverse events (AEs), risks identified through other sources, such as from experts in the field, State agencies that regulate ESD use, and records from the only facility that has recently manufactured and is currently using ESDs for SIB or AB, demand closer consideration. As discussed in the proposed rule, these sources further support the risks reported in the literature and indicate that ESDs pose additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling. State-of-the-art treatments for SIB and AB further demonstrate that the risks of ESDs for SIB or AB are unreasonable.

The ESDs subject to this ban are aversive conditioning devices intended to reduce or cease SIB or AB. Aversive conditioning pairs a noxious stimulus, such as a noxious electric shock delivered to an individual's skin by an ESD, with a target behavior such that the individual begins to associate the noxious stimulus with the behavior. The intended result is that the individual ceases engaging in the behavior and, over time, becomes conditioned not to manifest the target behavior. Some ESDs are intended for other purposes, such as smoking cessation; however, the ban includes only those devices intended to reduce or eliminate SIB or AB. ESDs are not used in electroconvulsive therapy, sometimes called electroshock therapy or ECT, which is unrelated to this rulemaking.

The effects of the shock are both psychological (including suffering) and physical (including pain), each having a complex relationship with the electrical parameters of the shock. As a result, the subjective experience of the person receiving the shock can be difficult to predict. Physical reactions roughly correlate with the peak current of the shock delivered by the ESD. However, various other factors such as sweat, electrode placement, recent history of shocks, and body chemistry can physically affect the sensation. As a result, the intensity or pain of a particular set of shock parameters can vary from person to person and from

shock to shock. Possible adverse psychological reactions are even more loosely correlated with shock intensity. The shock need only be subjectively stressful enough to cause trauma or suffering. Trauma becomes more likely, for example, when the recipient does not have control over the shock or has developed a fear of future shocks, neither of which is an electrical parameter of the shock.

In light of scientific advances, out of concern for ethical treatment, and in an attempt to create generalizable interventions that work in community settings, behavioral scientists have developed safer, successful treatments for SIB and AB. The development of the functional behavioral assessment, a formalized tool to analyze and determine triggering conditions, has allowed providers to formulate and implement plans based on positive behavioral techniques. As a result, multielement positive interventions (e.g., paradigms such as positive behavior support or dialectical behavioral therapy) have become state-of-the-art treatments for SIB and AB. Such interventions achieve success through environmental modification and an emphasis on teaching appropriate skills. Behavioral intervention providers may also recommend pharmacotherapy (the use of medications) as an adjunctive or supplemental method of treatment. Positive-only approaches have low risk and are generally successful even for challenging SIB and AB, in both clinical and community settings. The scientific community has recognized that

addressing the underlying causes of SIB or AB, rather than suppressing it with painful shocks, not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits.

Based on all available data and information, FDA has determined that the risk of illness or injury posed by ESDs for SIB or AB is substantial and unreasonable and that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury.

B. Summary of the Major Provisions of the Final Rule

This ban only includes aversive conditioning devices that apply a noxious electrical stimulus to a person's skin to reduce or cease aggressive or self-injurious behavior. The ban applies to devices already in commercial distribution and devices already sold to the ultimate (end) user, as well as devices to be sold or commercially distributed in the future. A banned device is an adulterated device, subject to enforcement action. The ban does not, however, prevent further study of such devices pursuant to an investigational device exemption, if the requirements for such are met.

C. Legal Authority

An ESD used for SIB or AB is a "device" as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to ban a device intended for human use by regulation if we find, on the basis of all available data and information, that such a device presents substantial

deception or an unreasonable and substantial risk of illness or injury, which cannot be corrected by labeling or a change in labeling. A banned device is adulterated except to the extent it is being studied pursuant to an investigational device exemption. This final rule is also issued under the authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

Under this final rule we are banning ESDs for SIB or AB. Because we lack sufficient information to quantify the benefits, we include a qualitative description of some potential benefits of the final rule. We expect that the rule will affect only one entity. In addition to the incremental costs this entity will incur to comply with the requirements of the final rule, the ban may create potential transfer payments of between \$14 million and \$15 million annually, either within the affected entity or between entities. The present value of total costs over 10 years ranges from \$0 million to \$44 million, with a primary estimate of \$22 million at a three percent discount rate, and ranges from \$0 million to \$38 million, with a primary estimate of \$18.8 million at a seven percent discount rate. Annualized costs range from \$0 million to \$5.0 million, with a primary estimate of \$2.5 million at a three percent discount rate, and range from \$0 million to \$5.0 million, with a primary estimate of \$2.5 million at a seven percent discount rate.

II. Table of Abbreviations and Acronyms

Abbreviation or acronym	What it means
AB	Aggressive behavior.
ABA	Applied behavior analysis.
ABC-I	Aberrant Behavior Checklist—Irritability (scale).
ADHD	Attention deficit hyperactivity disorder.
AE	Adverse event.
APA	American Psychiatric Association.
ASD	Autism spectrum disorder.
DBT	Dialectical behavioral therapy.
DDS	(Massachusetts) Department of Developmental Services.
DEEC	(Massachusetts) Department of Early Education and Care.
DMDD	Disruptive mood dysregulation disorder.
DPPC	(Massachusetts) Disabled Persons Protection Committee.
DSM	Diagnostic and Statistical Manual of Mental Disorders.
EA	Environmental assessment.
ESD	Electrical stimulation device.
FAS	Fetal alcohol syndrome.
FBA	Functional behavioral assessment.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FONSI	Finding of no significant impact.
GED	Graduated Electronic Decelerator.
ICD	Implantable cardioverter defibrillator.
JRC	Judge Rotenberg Educational Center, Inc.
MDD	Major depressive disorder.
NASDDDS	National Association of State Directors of Developmental Disability Services.
NDD	Neurodevelopmental disorder.
NYSED	New York State Education Department.

13314

Federal Register / Vol. 85, No. 45 / Friday, March 6, 2020 / Rules and Regulations

Abbreviation or acronym	What it means
PBS	Positive behavioral support.
PKU	Phenylketonuria.
PTSD	Post traumatic stress disorder.
SIB	Self-injurious behavior.
SIBIS	Self-Injurious Behavior Inhibiting System.
SNRI	Serotonin-norepinephrine reuptake inhibitor.
SSRI	Selective serotonin reuptake inhibitor.

III. Background and Determination

On April 25, 2016, FDA published a proposed rule to ban ESDs used to treat SIB or AB and requested comments on the proposal (81 FR 24386).¹ As explained in the proposed rule, ESDs for SIB or AB are aversive conditioning devices that apply a noxious electrical stimulus (a shock) to a person's skin to reduce or cease such behaviors. Although FDA cleared a few of these devices more than 20 years ago, due to scientific advances and ethical concerns tied to the risks of ESDs, state-of-the-art medical practice has evolved away from their use and toward various positive behavioral treatments, sometimes combined with pharmacological treatments. Only one facility in the United States has manufactured these devices or used them on individuals in recent years. As a result of this evolution in treatment over the past several decades, the available data and information on the risks and benefits of ESDs are limited.

A. Public Participation, Clarifications, and Key Changes

FDA convened a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee ("the Panel") on April 24, 2014 ("the Panel Meeting"), in an open public forum, to discuss issues related to FDA's consideration of a ban on ESDs for SIB or AB (see 79 FR 17155, March 27, 2014²; Ref. 1). FDA is not required to hold a panel meeting before banning a device, but FDA decided to do so in the interest of gathering as much data and information as possible, from experts in relevant medical fields as well as all interested stakeholders, and in the interest of obtaining independent expert advice on the scientific and clinical matters at issue. In considering whether to ban ESDs, FDA also conducted an extensive, systematic literature review to assess the benefits and risks

associated with ESDs as well as alternative treatments for patients exhibiting SIB and AB.

FDA invited interested parties to comment on the proposed rule by May 25, 2016. However, we received a request to extend the comment period and, in the *Federal Register* of May 23, 2016, we announced a 60-day extension, ending July 25, 2016 (81 FR 32258).³ In addition to requesting comments on the proposal generally, we specifically sought comments on the determinations that the risk of illness or injury posed by ESDs for SIB or AB is unreasonable and substantial, and that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury. We also sought comments on other issues related to the proposal to ban these devices.

FDA received more than 1,500 comments from several types of stakeholders. We received hundreds of comments from parents of individuals with intellectual and developmental disabilities. We received comments from several people who have themselves manifested SIB and AB in their lifetimes. We received submissions from dozens of State agencies and their sister public-private organizations. We received comments from the affected manufacturer and residential facility, some of its employees, and parents of individual residents. State and Federal legislators also expressed interest, as did State and national advocacy groups.

For this rulemaking, we also associated the Panel Meeting docket with this action (Docket No. FDA-2014-N-0238) and considered the approximately 300 comments submitted to the Panel Meeting docket. The types of stakeholders and the concerns they raised were similar to the comments on the proposed rule, in which we discussed many of the Panel Meeting comments in detail.

The overwhelming majority of comments supported this ban. The comments in opposition to this ban were primarily from the Judge

Rotenberg Center (JRC) and people affiliated with JRC; this includes comments made during the Panel Meeting and through submission of comments to the Panel Meeting docket. Specifically, these comments were from three former JRC residents, family members of individuals on whom ESDs have been used at JRC (one of the parents association comments included 32 letters from family members), a former JRC clinician, a Massachusetts State Representative, and one concerned citizen.

In its comments on the proposed rule, JRC included the hearing transcripts and exhibits from a recent Massachusetts court proceeding that considered the use of ESDs, in particular the Judge Rotenberg Center's (JRC's) graduated electronic decelerator (GED) devices. See *Judge Rotenberg Center, Inc., et al., v. Comm'r of the Dep't of Developmental Servs., et al.*, Docket No. 86E-0018-GI (Bristol, Mass. Probate and Family Court, June 20, 2018) (Mass. Docket No 86E-0018-GI). Therefore, some expert testimony from these transcripts is discussed in this final rule to the extent the testimony is relevant to the risks or benefits of ESDs for SIB or AB, or to the state of the art of treatment for this patient population.⁴ However, the issues in that State proceeding are different from the ones in FDA's ban proceeding, and the court's decision has no legal or scientific bearing on this ban.

The Bristol County (Massachusetts) Probate and Family Court considered whether a consent decree should be vacated based on significant changes in fact or law, in particular whether the professional consensus is that JRC's GED does not now conform to the accepted standard of care for treating individuals with intellectual and developmental disabilities. The court ultimately determined that no significant change in consensus warranted vacating the consent decree: "the evidence at the hearing did not establish that there is a professional consensus with respect to whether Level III aversive treatment [use of ESDs]

¹ Available at <https://www.federalregister.gov/documents/2016/04/25/2016-09433/banned-devices-proposal-to-ban-electrical-stimulation-devices-used-to-treat-self-injurious-or>.

² Available at <https://www.federalregister.gov/documents/2014/03/27/2014-06766/neurological-devices-panel-of-the-medical-devices-advisory-committee-notice-of-meeting-request-for>.

³ Available at <https://www.federalregister.gov/documents/2016/05/23/2016-12026/banned-devices-proposal-to-ban-electrical-stimulation-devices-used-to-treat-self-injurious-or>.

⁴ Any references to hearing transcripts or hearing exhibits herein refer to transcripts and exhibits from Mass. Docket No. 86E-0018-GI.

conforms to the accepted standard of care.” (Opinion at 48). The professional consensus regarding the accepted standard of care and such use of ESDs is not an issue in this ban. Rather, to ban a device under section 516 of the FD&C Act (21 U.S.C. 360f), FDA must determine the device presents an “unreasonable and substantial risk of illness or injury.” As explained in the proposed rule, in making this determination, FDA analyzes whether the risks the device poses to individuals are important, material, or significant in relation to its benefits to the public health, and FDA compares those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice (81 FR 24386 at 24388).

Compared to the proposed rule, we have made minor changes to the codified text of the classification regulation to make clear that only ESDs, not other aversive devices for SIB or AB, are banned. We have also added text to the device type classification to make clear that this ban is not a special control. We reconsidered a few of the representations and attributions of data and information made in the proposed rule. Our explanation of these changes, as well as our explanation why the revisions did not affect our overall evaluation of the benefit-risk profile and our ultimate conclusion with respect to the substantial and unreasonable risk of illness or injury from ESDs used for SIB or AB, are in section V.C. in the corresponding comment responses.

B. FDA’s Determination That ESDs for SIB or AB Present an Unreasonable and Substantial Risk of Illness or Injury

FDA considered all available data and information from a wide variety of sources, including the data and information submitted to the docket for the Panel Meeting and proposed rule: scientific literature, information and opinions from experts, information from State agencies that also regulate ESDs as well as their actions on ESDs, information from the affected manufacturer/residential facility, information from individuals subject to ESDs and their family members, and information from disability rights groups, other government entities, and other stakeholders. In weighing each piece of data and information, FDA took into account its quality, such as the level of scientific rigor supporting it, the objectivity of its source, its recency, and any limitations that might weaken its value. Thus, for example, we gave much more weight to the results of a study reported in a peer-reviewed journal by

an objective author than we did to anecdotal evidence.

As discussed in detail in the comment responses in section V, although we found that certain risks had weaker support than we asserted in the proposed rule, other information submitted in comments provided greater support for other risks. We continue to find that the medical literature shows that ESDs present a number of psychological risks including depression, PTSD, anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness; and the devices present the physical risks of pain, skin burns, and tissue damage. Because the medical literature suggests an underreporting of AEs, FDA carefully evaluated risks identified through other sources, such as from experts in the field, State agencies that regulate ESD use, and records from the only facility that is currently using ESDs for SIB or AB. As discussed in the proposed rule, these sources further support the risks reported in the literature and indicate that ESDs have been associated with additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling.

Although the available data and information show that some individuals subject to ESDs may exhibit an immediate interruption of the targeted behavior, the available evidence has not established a durable conditioning effect or an overall-favorable benefit-risk profile for ESDs for SIB or AB. No randomized, controlled clinical trials have been conducted, and the studies that have been conducted are very small and suffer from various limitations, including the use of concomitant treatments that make determining the cause of any behavioral changes difficult. The additional references cited in the comments on the proposed rule suffer from the same methodological and other limitations as those FDA considered previously, and the records and summaries JRC submitted regarding its residents constitute an even weaker source of evidence regarding the effectiveness of ESDs for SIB or AB.

State-of-the-art treatments for SIB and AB are positive-based behavioral approaches along with pharmacotherapy, as appropriate. The medical community now broadly recognizes that conducting careful functional assessments and addressing the underlying causes of SIB and AB

rather than suppressing behaviors with shocks not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits. As a result, research on the use of positive behavioral methods continues to grow; literature published since the proposed rule shows even greater success than described previously, as detailed in section V. Further, recent advancements in psychiatric research and clinical care have improved the understanding of psychiatric diagnosis and treatment, particularly in individuals with intellectual and developmental disabilities. This has facilitated the use of pharmacological treatments that reduce SIB and AB, whether the drug products target SIB or AB symptoms directly, regardless of the underlying condition, or by more indirectly reducing SIB and AB by improving the underlying condition. ESDs are only used at one facility in the United States on individuals from a small number of States, and there is evidence, including from the Massachusetts hearing, that the overwhelming majority of patients exhibiting SIB or AB throughout the country are being treated without the use of ESDs. Although positive behavioral interventions may not always be completely successful in all patients, the literature shows that they are typically successful, on their own or in conjunction with pharmacotherapy, regardless of the severity of the behavior targeted or the setting, and can achieve durable long-term results while avoiding the risks posed by ESDs.

Based on the serious risks posed by ESDs for SIB or AB, the inadequacy of data to support their effectiveness, and the positive benefit-risk profiles of the state-of-the-art alternatives for the treatment of SIB or AB, FDA has determined that the risks posed by ESDs for SIB or AB are important, material, or significant in relation to their benefits to the public health, and that ESDs present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. FDA has decided to ban these devices under section 516 of the FD&C Act. This rule applies to devices already in distribution and use, as well as to future distribution of these devices. The vulnerable population subject to ESDs for SIB or AB, like all individuals, are entitled to the public health protections under the FD&C Act.

IV. Legal Authority

An ESD used for SIB or AB is a “device” as defined under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). Section 516 of the FD&C Act authorizes FDA to ban a device

intended for human use by regulation if it finds, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury, which cannot be corrected or eliminated by labeling or change in labeling (21 U.S.C. 360f(a)(1) and (2)). A banned device is adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), except to the extent it is being studied pursuant to an investigational device exemption under section 520(g) of the FD&C Act (21 U.S.C. 360j(g)). This rule is also issued under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which provides authority to issue regulations for the efficient enforcement of the FD&C Act.

In determining whether a deception or risk of illness or injury is “substantial,” FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing (see 21 CFR 895.21(a)(1)). Although FDA’s device banning regulations do not define “unreasonable risk,” in the preamble to the final rule issuing 21 CFR part 895, FDA explained that, with respect to “unreasonable risk,” we will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users (44 FR 29214 at 29215, May 18, 1979).⁵ The state of the art with respect to this rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior.

Thus, in determining whether a device presents an “unreasonable and substantial risk of illness or injury,” FDA analyzes the risks and the benefits the device poses to individuals, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information (H. Rep. 94–853 at 19; 44 FR 29214 at 29215).

Whenever FDA finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or

has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device (see 21 CFR 895.20). If FDA determines that the risk can be corrected through labeling, FDA will notify the responsible person of the required labeling or change in labeling necessary to eliminate or correct such risk (see 21 CFR 895.25).

FDA notes that a banned device is not barred from clinical study under an investigational device exemption pursuant to section 520(g) of the FD&C Act. However, any such study must meet all applicable requirements, including but not limited to, those for: protection of human subjects (21 CFR part 50), financial disclosure by clinical investigators (21 CFR part 54), approval by institutional review boards (21 CFR part 56), and investigational device exemptions (21 CFR part 812).

V. Comments on the Proposed Rule and FDA’s Responses

In the proposed rule, in addition to seeking comment on our determination of substantial and unreasonable risk that cannot be corrected or eliminated with a change in labeling, we sought comments on other issues such as how long transitions away from ESDs for SIB or AB may take as well as the proposed effective date. We also requested comments on the proposed regulatory impact (economic) analysis. We have divided the comments and responses by subject matter, organized like the proposed rule: background information, evidence interpretation, risks of ESDs for SIB or AB, effects of ESDs on SIB or AB, state-of-the-art for the treatment of SIB or AB, labeling and correcting or eliminating risks, legal issues, and finally, transition time. Of the comments to the docket, the overwhelming majority supported a finding of substantial and unreasonable risk that cannot be corrected or eliminated with a change in labeling. The comments related to transitioning away from ESDs for SIB or AB, as well as the proposed effective date, supported no transition time and an immediate effective date. We received no comments on the proposed regulatory impact analysis.

Any comments received relating to ECT are outside the scope of this rulemaking, and consequently, we do not address those comments. We issued a Final Order on ECTs in 2018. (see 83 FR 66103, December 26, 2018).⁶

⁵ Available at <https://www.federalregister.gov/documents/2018/12/26/2018-27809/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-effective-date-of>.

⁶ Available at <https://www.govinfo.gov/content/pkg/FR-1979-05-18/pdf/FR-1979-05-18.pdf>.

We describe and respond to the comments in this section. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment’s value or importance or the order in which comments were received. As most of the comments support this ban without raising questions or concerns, our responses primarily relate to the few comments that do not support the ban.

A. Background Information About ESDs, SIB, and AB

(Comment 1) A comment states that FDA’s characterization of behaviors associated with SIB and AB is broadly true but does not adequately convey the extreme behaviors exhibited by some individuals on whom ESDs are used. The comment states that such behaviors can put both the patients and caregivers at immediate risk of irreparable, serious, and even life-threatening injury.

(Response) FDA agrees with the commenter that in some cases the behaviors exhibited by individuals with SIB or AB are extreme and could cause serious injury to the individual or their caregiver. As stated in the proposed rule, SIB commonly includes: Head-banging, hand-biting, excessive scratching, and picking of the skin. However, SIB can be more extreme and result in bleeding; broken and even protruding bones; blindness from eye-gouging or poking; other permanent tissue damage; or injuries from swallowing dangerous objects or substances. AB involves repeated physical assaults and can be a danger to the individual, others, or property. We referred in the proposed rule to a JRC submission that states a link between SIB and death. Thus, FDA has taken into account the extremity of behaviors associated with SIB and AB.

(Comment 2) A comment states that FDA incorrectly defined the intended use population for ESDs and, in doing so, overstated the limited patient population that uses ESDs for SIB or AB. The commenter asserts that FDA has performed an erroneous benefit-risk analysis by “improperly inflating the intended use population by orders of magnitude.”

(Response) FDA disagrees with this assertion. The commenter has incorrectly interpreted FDA’s estimates,

which we explained in the proposed rule. The commenter focuses on the narrow “patient population that uses ESD therapy for SIB and AB” whereas FDA’s estimate more broadly refers to the total number of individuals in the United States who exhibit SIB and AB (330,000) and the number of the most extreme cases (25,000), regardless of how they are treated (81 FR 24386 at 24389).

We based these numbers on the scientific literature, which shows that the prevalence of SIB in individuals with intellectual or developmental disabilities ranges from 2.6 percent to 40 percent, or 2 to 23 percent in community samples (Ref. 2). More recently, one analysis found a prevalence of SIB in a clinical population of children with developmental disabilities at 32 percent, suggesting that the actual prevalence may be at the high end of earlier estimates (Ref. 3). Further, estimates of the prevalence of AB in individuals with intellectual or developmental disabilities range as high as 52 percent, though 10 percent is more commonly reported (Ref. 2). Thus, by conservative estimates, based on a population of 330 million in which 1 to 3 percent of individuals have intellectual or developmental disabilities (and counting only them, not all people who manifest SIB or AB), at least 330,000 people in the United States manifest SIB, AB, or both; less conservative estimates are much higher (see Ref. 2).

Elsewhere in its comments, the commenter, JRC, appears to agree with FDA’s estimates of 330,000 and 25,000 but explains that it enrolls an even smaller subset of the most severe, refractory residents. This represents, in its view, the totality of the intended use population for ESDs for SIB or AB, which in 2016 numbered 51 individuals from 12 States.

FDA does not contest that ESDs for SIB or AB were, in 2016, used on about 51 individuals in the United States, or that these individuals come from 12 States (in the proposed rule, FDA estimated the number of States to be 6–11 (81 FR 24386 at 24408)). Indeed, as explained in the comment responses about the state of the art, the professional field, with the sole exception of JRC, has moved beyond the use of ESDs for SIB or AB. However, FDA continues to believe that 25,000 is a reliable, conservative estimate for the number of the more extreme cases of SIB and AB in the United States. We have no evidence establishing that, of those, JRC receives the most extreme or refractory cases. The comment does not provide evidence of this other than

contending that ESDs are only used after all alternative treatments have failed and offering some documentation purporting to show as much. This does not mean that JRC is unique in encountering severe cases. Rather, this shows that JRC is unique in which methods it chooses to employ. We have evidence that extreme cases are treated elsewhere in the United States without the use of ESDs, as discussed in more detail in the comment responses regarding the state of the art. Thus, in considering the number of more extreme cases in the United States compared to the limited number and geographic origins of patients subject to ESDs at JRC, we continue to believe that JRC’s patients are not uniquely refractory or responsive to ESDs.

(Comment 3) A comment argues that applying the ban only to a discrete use of ESDs in one type of patient population, instead of all aversive conditioning devices, is arbitrary. The comment specifically outlines several shock aversive products and uses that FDA is not proposing to ban, including skin shock products for smoking cessation, alcohol and drug addiction, and other “bad habits,” shock aversives for inappropriate sexual behavior after traumatic brain injury, and shock aversives for nonsuicidal self-injury cutting behaviors. The commenter states that FDA has not provided a discussion or rationale distinguishing why the risks of skin shock are acceptable for these devices for these other conditions and not for the treatment of patients with SIB and AB. The commenter further argues that FDA’s distinction based on patient control over the shocks is misplaced because in all cases, parental or guardian consent is required and obtained.

(Response) The commenter is correct in that this rule only applies to ESDs for SIB or AB and not to ESDs for other intended uses. FDA explained in the proposed rule that, although these products have parallels in technology and behavior modification strategy, products for other uses address different conditions or behaviors in different patient populations, and as a result, they present different benefit-risk profiles. We explained, for example, that many people who exhibit SIB or AB have disabilities that present vulnerabilities, such as difficulty communicating pain and other harms caused by ESDs, not likely to be present in people who use ESDs for other purposes. As a result, individuals who exhibit SIB or AB would bear a higher risk of injury or illness from the shock than, for example, smokers who choose to use an ESD to help quit smoking.

Smokers can immediately communicate pain to the device’s controller or remove the device themselves. They can communicate symptoms of other harms that may be caused by ESDs to their healthcare provider, which may lead to discontinuation of the device’s use, or decide to stop using the device. In addition, people who exhibit SIB or AB may not be able to associate cause and effect or, as with some people with an autism spectrum disorder (ASD), they may express pain atypically or not at all.

ESDs for other intended uses also differ from ESDs for SIB or AB with respect to whether the individual subject to the shocks has control over them as well as the level of control they have. FDA recognizes that, at the facility that still uses ESDs for SIB or AB, legal consent is obtained to use the devices. However, the person who provides legal consent is typically not the person subject to the risks of the use of the device. This distinction is significant because consent does not mitigate the risk in that the person subject to the risk has no control over use of the device. For example, a person who fears future shocks could not opt out and thereby reduce the fear. Similarly, a person who experiences extreme pain or suffering could not opt out to avoid those harms in the future. FDA is not questioning the validity or importance of legal consent, but rather pointing out that legal consent does not eliminate concerns related to the shock recipients’ communication difficulties and lack of control over use of the device on them.

B. Evidence Interpretation

(Comment 4) Many comments state that FDA’s analysis for the proposed rule was thorough and well supported. Some of them characterize the evidence for the ban as strong and contrast that with the evidence for the effectiveness of ESDs for SIB or AB, which they characterize as weak.

(Response) FDA agrees. As we stated in the proposed rule, FDA first conducted an extensive, systematic literature review to assess the benefits and risks associated with ESDs as well as the state of the art of treatment of patients exhibiting SIB or AB. As we explained in the proposed rule, SIB and AB were considered in tandem, and these conditions presented in individuals with intellectual and developmental disabilities, such as ASD, Down syndrome, Tourette’s syndrome, as well as other cognitive or psychiatric disorders and severe intellectual impairment (including a broad range of intellectual measures). The studies encompassed both children and adults.

As noted in section III.B, FDA convened the Panel Meeting on April 24, 2014, in an open public forum, to discuss issues related to FDA's consideration of a ban of ESDs for SIB or AB (see 79 FR 17155). Although FDA is not required to hold a panel meeting before banning a device, FDA decided to do so in the interest of gathering as much data and information as possible, from experts in relevant medical fields as well as all interested stakeholders, and in the interest of obtaining independent expert advice on the scientific and clinical matters at issue. Eighteen panelists with expertise in both pediatric and adult patients represented the following biomedical specialties: Psychology, psychiatry, neurology, neurosurgery, bioethics, and statistics; panelists included representatives for patients, industry, and consumers (Ref. 4). FDA provided a presentation that described the banning standard, the regulatory history of aversive conditioning devices, alternative treatments, and a summary of the benefits and risks of ESDs, including a comprehensive, systematic literature review based on the information available at that time (see generally Refs. 5 and 6). After the Panel Meeting, FDA reviewed approximately 300 comments submitted to the public docket created for the Panel Meeting (Docket No. FDA-2014-N-0238). FDA associated that docket with this rulemaking and considered those comments in this rulemaking, as appropriate.

(Comment 5) A comment asserts that FDA ignored, misrepresented, and distorted the available information and data, favoring evidence that supports the ban while dismissing evidence that supports the use of ESDs for SIB or AB.

(Response) FDA disagrees and addresses the commenter's assertions regarding specific information and data in separate comment responses in this final rule. FDA has thoroughly and fairly reviewed the available data and information, with multiple opportunities for input from stakeholders on all sides of the issue. FDA considered all additional information timely submitted to the docket in this rulemaking, including comments by the public. The public comments included data and information as well as court documents (including transcripts and exhibits) from litigation related to the use of ESDs for SIB or AB. In some cases, as explained in responses to various comments, the comments led FDA to reconsider and change its evaluations of particular sources. In other cases, the docket information repeated previously

received material, thus reinforcing our evaluation. Some information was not relevant, for example, when it sought to refute a premise that FDA did not rely upon in the proposed ban.

However, FDA did not dismiss evidence that supports the use of ESDs for SIB or AB. We weighed all available data and information, taking into account its quality, such as the scientific rigor supporting it, the objectivity of its source, its recency, and any limitations that might weaken its value. Scientific rigor is greater when the study includes randomization or other controls and covers a large number of subjects. For less controlled studies, such as a case report, a greater number of study subjects across many reports will generally bolster confidence, for example, when many case reports are examined within a meta-analysis. Thus, we generally gave more weight to observations under controlled conditions than to reports of anecdotes. Similarly, peer review bolsters confidence because the process allows other experts to question or critique potential inaccuracies or errors. We generally gave more weight to the results of a study in a peer-reviewed journal than we did to non-peer-reviewed papers.

We considered the opinions of Panel members and other experts, some of whom support the use of ESDs for SIB or AB and some of whom do not. We generally gave more weight to expert opinions about scientific subjects than opinions from laypersons about scientific subjects. Although expert opinions are generally weaker scientific evidence than studies, the weight of such opinions is increased, for example, when they report data or include confirmatory or supportive citations to peer-reviewed scientific references, the subject matter is within the offeror's expertise, the opinion is based on regular professional practice or first-hand experiences, and/or the offeror is free from conflicts of interest. We considered opinions from commenters and others, including individuals at JRC, their parents, JRC staff, and JRC itself although such opinions merit relatively less weight in drawing scientific conclusions.

We explained in the proposed rule, and throughout this final rule, how this evidence relates to our conclusions and the strength of the evidence as it pertains to those conclusions. While the commenter may or may not agree with how we weighed any given piece of evidence, FDA did not ignore, misrepresent, distort, dismiss or favor evidence merely because it supported a particular result.

(Comment 6) A comment argues that FDA dismisses evidence supporting the benefits of ESDs for SIB or AB because of various weaknesses yet accepts evidence of risks that may have the same weaknesses.

(Response) FDA disagrees. FDA considered all available data and information, derived from a variety of sources and methods. As discussed in Responses 5 and 7, because the strength of different data and information—for example, from the scientific literature, experts, and various stakeholders—varied greatly, we weighed the evidence accordingly. Although the commenter may disagree with how FDA weighed the evidence, we did not dismiss evidence.

With respect to accepting evidence of risks from sources that exhibit weaknesses, we explain throughout this rulemaking that we believe AEs have been underreported and the reasons why (see Responses 26 to 28). Information submitted to FDA after the proposal supports that proposition and has helped us, upon further consideration, to update our evaluation. For example, as explained in Response 13, we believe the proposed rule understated the risk and harm of pain. We believe that the risk of pain is greater and that the harm of pain is more frequent than stated in the proposed rule.

In other cases, we explain that we evaluated particular risks consistent with our view of the weight of evidence. For example, we explain in Response 24 that the risk of seizures is not well established, in part because the information came from individuals who attributed their seizures to ESDs, lay people, as well as advocacy groups that stated shocks could trigger seizures (as opposed to, *e.g.*, peer-reviewed scientific articles). Because we did not accord this information significant weight, it did not greatly affect our evaluation of the benefit-risk profile.

As another example, the commenter argues that we have identified the risk of suicidality based on anecdotes from individuals who were subject to ESDs and that suicidality was not related specifically to ESD application. The comment highlights an individual who experienced suicidal ideation yet later credited use of the ESD for saving her life by replacing what the commenter describes as “ineffective and harmful psychotropic medication.” To support this risk of ESDs for SIB or AB, we explained in the proposed rule that experts in the field of behavioral science (including members of the Panel) and State agencies that regulate ESDs indicate that the devices have been

associated with short- and long-term trauma, including suicidal ideation (81 FR 24386 at 24399). Given that ESDs can also contribute to stress, anxiety, learned helplessness, and posttraumatic reactions, among other outcomes, we do not believe that it is reasonable to conclude that the risks presented by ESDs are unrelated to suicidal ideation.

The individual's belief that an ESD helped her does not speak to whether suicidal ideation is a risk posed by the device. FDA has no reason to doubt that she experienced suicidal ideation or that it stopped and she felt better. However, her statement is not strong evidence for the effects of ESDs on the processes underlying the ideation; the statement is not offered by an expert in the field and is not a result from a clinical study under controlled conditions. Such a statement, for example, does not rule out the possibility that concurrent therapies were responsible for the improvement, nor does it necessarily represent any other individual's point of view. It also does not provide any basis for concluding that state-of-the-art therapies, properly attempted and continuously administered, would not have succeeded.

In another instance, the comment criticizes FDA for using a double standard when presenting and evaluating data by quoting an expert in a media report who explained that an individual went into a catatonic condition after an ESD was used on him. However, this was one of multiple sources FDA relied on for this risk. We explained that catatonia may be an additional risk based on scientific literature that describes catatonic sit-down associated with the use of ESDs, and statements and comments from individuals on whom ESDs have been used, their family members, disability rights groups, and others. Because the statement appeared in a media report, we did not accord it the same weight as the information in the scientific literature.

It is also important to understand that the premise of the critique—that the same type of evidence should support establishing benefits if it supports identifying risks—is flawed. For example, FDA has long recognized that isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness, but that such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable (see 21 CFR 860.7(c)(2)).

The same general principle applies here. While the evidence purporting to show the benefits of ESDs for SIB or AB is insufficient to establish the effectiveness of the device, the same type of evidence may provide useful risk information. For example, an isolated case report that describes an initial increase in self-mutilative behavior following ESD application indicates to FDA that an initial increase in self-mutilative behavior is a risk even though the same report would not meet the threshold of evidence to establish effectiveness. This does not mean that any type or amount of evidence is sufficient to support a risk of harm; it means only that certain evidence that may be inadequate to establish effectiveness may nonetheless be adequate to support certain risks.

(Comment 7) A comment states that, in FDA's Executive Summary for the Panel Meeting, we noted that the majority of behavioral studies identified prior to the Panel Meeting were confined to small sample sizes or case reports. The comment asserts that those limitations have not stopped FDA from relying on literature about positive behavioral support (PBS), while FDA dismisses evidence supportive of ESDs because of those same limitations.

(Response) FDA disagrees. The comment incorrectly attributes a description from the Executive Summary to materials that FDA identified after the Panel Meeting. Since the Panel Meeting, FDA identified additional information and data, including behavioral studies with larger numbers of subjects. Additionally, as explained elsewhere, although the commenter may disagree with how FDA weighed the evidence, FDA did not dismiss evidence due to small sample sizes or the fact that they were case reports. However, these factors did result in FDA assigning relatively less weight than we would to a more robust design such as a randomized controlled trial with a large number of subjects.

With respect to the evidence supportive of ESDs, the only article specifically about JRC's GED device was published in a peer-reviewed journal over a decade ago, and it studied only nine subjects at JRC (Ref. 7). Studies of ESDs more generally have been published in peer-reviewed journals, but many of them are decades old. In the intervening decades, the understanding of pathophysiology has evolved as has the ability to identify and systematically record AEs. These developments are alongside heightened peer-review standards for study and reporting. Accordingly, it is reasonable to assign these studies less weight than more modern studies.

Since the Panel Meeting, FDA identified several studies of PBS in peer-reviewed journals that include more subjects, systematically record AEs, and benefit from recent (not decades-old) knowledge. For example, a recent single meta-analysis of PBS that FDA identified after the Panel Meeting synthesized information from 423 case reports (Ref. 8), whereas JRC has stated in a comment that it only applied its GED to 269 individuals since 1990. The peer-reviewed data and information about PBS were published more recently and better reflect modern scientific advances and contemporary ethical standards of the profession. The evidence also adheres to modern, more exacting peer-review standards for study conduct and reporting. Recent studies also benefit from the improvements in functional analysis and teaching adaptive or replacement behaviors that began in the mid-1980s (see Ref. 9). Refinement and application of such knowledge increases the success of the behavioral interventions (see Ref. 10). Further, more-modern study designs that include more coded baseline and treatment data points correlate with clearer demonstrations of treatment effects (see Ref. 10). Another benefit is that relatively recent studies of behavioral treatment of SIB more often report results that are generalizable across settings (see Ref. 11). Modern study designs are also more reflective of contemporary ethics and practice, making their results more relevant to treatment (see Ref. 12, discussing outmoded nomenclature and setting to study the effects of contingent shock on body rocking). It is noteworthy that even recent meta-analyses that included punishment techniques did not include the use of ESDs (see, e.g., Ref. 10); one Panel member described the modern attitude toward ESDs for SIB or AB as "wholesale abandonment." To summarize the advantages of more-recent data, the quality and quantity of the available data tend to be higher, they tend to show clearer effects, and the corresponding refinement in techniques leads to greater treatment success.

Therefore, although some PBS studies rely on small sample sizes or are case reports, the overall number of subjects who have been studied is significantly larger than for ESDs for SIB or AB. More robust analysis has been conducted on these subjects, and the data and information are more recent, more reflective of scientific advances and modern ethical standards, and held to a higher peer-review standard. Thus, we believe we have appropriately weighed the evidence and disagree that we

should have considered the various studies to be of equivalent weight.

(Comment 8) A comment criticizes the 2006 New York State Education Department (NYSED) report on JRC as misleading and biased and questions FDA's reliance on the report. The comment points to an earlier NYSED report from 9 months prior that was more favorable to JRC.

(Response) FDA disagrees that the report is misleading and biased. As the 2006 report states, the NYSED undertook a review based on documentation it received subsequent to its 2005 inspections (Ref. 22). That documentation, according to NYSED, "raised concern about JRC's use of aversive interventions, as well as recent questions from legislators." The 2005 Special Education Quality Assurance Nondistrict Program Review, the earlier NYSED report, was more general, focusing on "areas of greatest significance to the health and safety and provision of special education programs and services." In contrast, the 2006 Observations and Findings of Out-of-State Program Visitation was specifically conceived "to gain an understanding of the scope of the behavior intervention plans," paying particular attention to: (1) Health and safety issues related to the use of aversive interventions; (2) the general standard for implementing and monitoring behavior plans; (3) whether the interventions were commensurate with the individuals' behavioral difficulties; and (4) to determine if individuals were receiving interventions consistent with individualized education programs.

Although the 2005 Program Review and the 2006 Observations and Findings both examine practices at JRC, their scope and purpose are separate and distinct. Further, the 2005 document contemplated all students from New York, whereas the 2006 document considered those whose behavioral intervention plans included the use of ESDs. Thus, to the extent these documents shed light on the use of ESDs for SIB or AB, the 2006 document is more relevant than the 2005 document.

To provide context, the NYSED has itself submitted a docket comment consistent with their 2006 report (Ref. 23). Specifically, regarding the necessity of ESDs, the NYSED 2006 report relied in part on three behavioral psychologists serving as independent consultants. The NYSED in 2006 also conducted interviews with individuals at JRC. FDA believes it reasonable to give more weight to the 2006 report because, unlike the 2005 report, its

objective was to examine the use of ESDs for SIB or AB, and it included evaluations from independent behavioral psychologists as well as the results of patient interviews.

(Comment 9) A comment asserts that, because FDA did not visit JRC and meet with its staff or obtain firsthand observations of residents, we did not educate ourselves on the complete facts regarding JRC's use of the device. The comment contrasts this with what it characterizes as ex parte discussions with other parties, including three former residents who approached FDA.

(Response) While FDA did not directly observe residents in JRC's facility, it did not need to do so to obtain relevant information for this rulemaking. Such observations are not necessary for FDA to understand JRC's use of ESDs or, more importantly, the risks and benefits of ESDs for SIB or AB. Such observations would not be part of a trial or study, nor would they proceed according to experimental controls that could allow observers or analysts to draw generalizable conclusions. Any observation may or may not be typical, whether by chance or, for example, because a tour at JRC's invitation would be controlled or the areas and individuals available for observation would not be representative. Elsewhere, this commenter criticizes the incorporation of anecdotal data and information; information obtained by FDA on such a tour would likely be subject to the same criticism.

Further, we have information about the residents at JRC and their views, including firsthand accounts. JRC has provided FDA with pictures and short biographies of many JRC residents. It has also provided copies of emails expressing individuals' sentiments that are favorable to JRC. During the Panel Meeting, individuals at JRC, including representatives of JRC, presented their views. FDA also conducted inspections of JRC.

While FDA had discussions with three former residents prior to issuing the proposed rule, to the extent we relied on these communications, we summarized the relevant content and provided our rationale in the proposed rule. The public had an opportunity to review this information and comment on it.

(Comment 10) A comment asserts that phone interviews conducted by FDA with individuals formerly at JRC were anecdotal and unscientific, yet the comment also claims that FDA dismissed clinical data from JRC and did not interview patients and parents who support the use of ESDs for SIB or AB. The commenter also states that FDA

did not consider data from 269 individuals at JRC since 1990 and argues that such data plainly demonstrate the effects of ESDs on SIB and AB.

(Response) FDA disagrees that we dismissed any data, either clinical data from JRC or the views of individuals at JRC and parents who support the use of ESDs for SIB or AB. We explained in the proposed rule and elsewhere in this final rule how this evidence relates to our conclusions and the strength of the evidence as it pertains to those conclusions. We considered all commenters' stated opinions and weighed them appropriately when drawing scientific conclusions. FDA considered all data and information, including anecdotal evidence relating to the individuals and families with current or former experience with JRC's use of ESDs for SIB or AB. However, we agree with the commenter that anecdotal evidence should not be accorded the same weight as scientific evidence, and we weighed such evidence accordingly. Obtaining views from all perspectives, including highly personal information, proved helpful in understanding perspectives on the use of ESDs.

Although FDA did not conduct interviews with individuals currently at JRC or their parents, they have had the opportunity to submit comments in the context of the Panel Meeting and proposed rule. Two associations of family members of individuals at JRC submitted comments to the Panel Meeting docket opposing a ban (one of the comments included 32 letters from family members). At the Panel Meeting, one parent and three individuals at JRC spoke in opposition to the ban. In the docket for the proposed rule, we received a brief from JRC parents' counsel, letters through counsel from parents of individuals at JRC, as well as other individual comments opposing the ban, primarily from those associated with JRC. Additionally, a comment alluded to an editorial in a national newspaper and included copies of emails apparently meant to convey that individuals formerly at JRC are grateful for their time at JRC.

Furthermore, although the commenter may disagree with how FDA weighed the evidence, FDA did not dismiss clinical data from the manufacturer (see Response 26; see also Responses 18, 38, and 39, discussing other records). As explained elsewhere, we believe the available data and information, including that from the manufacturer, JRC, underreport AEs (see Responses 26 to 28). Noting such omissions or weaknesses in the data and information

is not to dismiss it but rather to explain why it does not necessarily show what the commenter argues, much less show as much conclusively. Likewise, as explained in Responses 33, 34, 38, and 39, we found that because of the multitude of flaws and weaknesses, the data and information provided by JRC do not establish durable effectiveness. For instance, the data do not represent *study* data but rather only resident records; the data and information fail to adequately detail behaviors prior to ESD use, formal functional assessments, important aspects of device application and data collection; and the data fail to account for effects from concurrent treatments. We disagree that we did not consider this data, and upon consideration, find the data do not demonstrate the effectiveness of ESDs for SIB or AB.

(Comment 11) A comment asserts that parent- and patient-centric perspectives deserve more weight than unnamed parents' perspectives reported to researchers who used pseudonyms for publication. The commenter prefers "parents who communicated on the record, direct and unfiltered."

(Response) FDA disagrees. The fact that a researcher does not identify parents by name does not make those parents' perspectives less relevant or useful. FDA notes that the same comment elsewhere states that FDA should discount certain parent- and patient-centric perspectives that disagree with the commenter, even when those parents and patients used their names and submitted their perspectives for the record. Further, the comment does not explain why the fact that a researcher does not identify an individual impacts reliability. Nevertheless, when we discussed the opinions of unnamed parents in the proposed rule, we noted that we could not conclude that the experiences reported by those who volunteered to share negative experiences were shared by others or are generally representative of families' experiences with JRC. We have weighed the perspectives with these considerations in mind.

(Comment 12) A comment criticizes FDA for relying on unsourced letters and papers and unscientific news articles with quotes from lay people.

(Response) As explained elsewhere, FDA considered opinions from experts and lay people, and we took into account whether opinions were offered by experts or supported by research, among other factors. Opinions offered by behavioral experts about the treatment of SIB and AB are afforded more weight than laypeople's opinions about the treatment of SIB and AB;

those expert opinions carry yet more weight when, for example, they cite peer-reviewed research. Regarding sourcing, since all of the references that the comment critiques as unsourced were attributed to specific authors and institutions, FDA fails to understand this criticism. Additionally, the sourcing provided FDA with the information needed to determine the weight to give each reference. Each reference was available for review during the comment period, so the commenter had an opportunity to comment on their substance.

In terms of weighing the evidence from the references the commenter cites, we recognize, for example, that Dr. Donnellan wrote a letter that was not peer-reviewed. However, because Dr. Donnellan has expertise in the field, the content of the letter merits more weight than laypeople's opinions. So too does the chapter authored by Drs. LaVigna, Willis, and Donnellan because of the authors' expertise in the subject matter. Moreover, a named editor reviewed the information, which merits additional weight compared to unedited documents, even those from experts. Regarding the report from NYSED, FDA believes that agency's responsibility and expertise to assess such information, as well as draw conclusions from that information, is relevant in determining how much weight to give the report.

With respect to the news article referred to by the commenter, FDA cited it solely with respect to our assessment of the state of the art, to support the fact that one of the pioneers of ESDs publicly repudiated contingent shock for a lack of effectiveness, and not as part of our determination that the evidence fails to establish ESD effectiveness. We believe it is appropriate to cite this type of source for this limited point. Further, FDA notes that the commenter elsewhere implores FDA to heed views presented in a newspaper, including speculation by Dr. Israel, in an attempt to make a point regarding ESD effectiveness and the lack of effectiveness of alternatives (Ref. 13). In that case, the commenter relies on the newspaper article to make conclusory claims about the negative effects of removing ESDs. Even putting aside the relative weakness of this source, the newspaper article makes clear that the individual's treatment plan consisted of many elements in addition to ESDs, and that the individual subject to shocks increasingly "could not accept the price of this improvement," the improvement being an average of fewer than 200 shocks per month in connection with decreased self-mutilation. We do not

agree with the commenter's criticisms and elsewhere explain how we weighed various types of information differently.

C. Risks of ESDs for SIB or AB

(Comment 13) A comment argues that FDA's evaluation of the benefit-risk profile of ESD use is fundamentally flawed because the risks did not materialize into harms. The comment also argues that FDA failed to account for the risks posed by banning the device, which the comment characterizes as a "life-saving therapy."

(Response) FDA disagrees that we have overstated risks and have not accurately evaluated the benefit-risk profile in consideration of those risks. Risks do not need to have materialized into harms to be relevant because proof of harm is not required under the banning standard. Further, some of the risks posed by ESDs have materialized into harm, including intense pain. The commenter itself recognizes that there are potential risks associated with use of ESDs. It refers to a consent form listing some of the risks, which are consistent with FDA's analysis in the proposed rule:

The potential physical risks associated with the GED may include temporary skin redness, which clears up within a few minutes or a few days at most, and there is a possibility that a small blister may appear. JRC rotates the placement of the electrodes to avoid superficial red marks or scaling of the skin. The psychological/behavioral risks that might be associated with the GED include anxiety (nervousness, tensing muscles) during the period between the occurrence of the behavior and the occurrence of the programmed consequence, escape responses and short-term or long-term collateral effects including: nightmares; intrusive thoughts; avoidance behaviors; marked startle responses; mistrust; depression; flashbacks of panic and rage; anger; hyper-vigilance; and insensitivity to fatigue or pain.

The form adds to the evidence in the proposed rule, among other information, that the shock "is intended to function as a painful stimulus." In the proposed rule, although we provided, for example, descriptions of individuals who experienced ESDs describing the shock as "a thousand bees stinging you in the same place for a few seconds," we also noted information from JRC suggesting that the electric current may not be great enough to cause pain and its statements that the shock "may be" painful to some patients (81 FR 24386 at 24397). Since then, behavioral experts testified in the Massachusetts hearing regarding the level of pain caused by ESDs based on their personal experience with ESD shocks. For example, they testified the shocks felt "excruciatingly painful," "extremely painful," "quite

painful,” like a “bulging and a ruptured disc,” and “the most painful thing I’ve ever experienced.” (Ref. 14, respectively: day 7 at 161; day 9 at 82; day 21 at 81–82; day 13 at 218.) In light of this new information from JRC and the experts in the Massachusetts hearing, we believe that the proposed rule understated pain as a harm caused by ESDs.

The pain ESDs cause is relevant because, although ESDs are intended to apply an aversive stimulus, the pain they cause to develop the aversion is nevertheless harmful. We also noted that JRC does not include pain in its discussion of AEs caused by the device, yet when JRC’s Dr. Nathan Blenkush was asked directly whether the stimulus causes pain, he answered “yes” (81 FR 24386 at 24397; see also Ref. 15 at 123). People affiliated with JRC, including Drs. Edward Sassaman and Anthony Joseph, have stated that they observed no harms in many years of observing individuals subject to ESDs, so they appear not to consider certain adverse effects, including pain, to be harms. As stated in the proposed rule, such a view is in line with decades-old research that considered pain or discomfort to be an indicator of effectiveness (81 FR 24386 at 24397). However, this is not consistent with contemporary standards, and we conclude that pain caused by the devices is a harm. Far from overstating risks because they have not materialized into harms, FDA believes that JRC has understated realized harms, and the proposed rule understated at least the degree of harm of pain.

With regard to the risks of the ban itself, FDA has considered the risks of the use of ESDs for SIB or AB in light of the state of the art for SIB and AB and determined that they are substantial and unreasonable. In contrast, as discussed in section V.E, state-of-the-art therapies such as PBS pose little to no risk and are generally successful regardless of the severity of the target behavior. FDA acknowledges that a small subpopulation of people who manifest SIB or AB may simply have no adequate treatment option. However, this does not mean that ESDs are effective for that subpopulation or that such individuals would be harmed if ESDs were not available. Claims that the use of ESDs is necessary for some people are not supported by the available data and information.

(Comment 14) A comment asserts, while recognizing that pain has a subjective element, that the shock delivered by an ESD is not capable of physical harm to the patient, such as skin burns or other damage to the body

or impairment of any bodily functions. The comment asserts that FDA’s clearance of the GED–1 included review of data on pain perception levels submitted by JRC.

(Response) FDA agrees that pain has a subjective element, but disagrees with the suggestions that pain is not a physical harm, or a harm at all. As we explained in the proposed rule, although physical reactions roughly correlate with the peak current, shock intensity and its effects can also vary from person to person based on the amount of sweat on the skin, electrode placement, recent history of shocks, and body chemistry, among other factors (81 FR 24386 at 24387). Further, adverse psychological reactions are even more loosely correlated with shock intensity (see 81 FR 24386 at 24387). As such, the intensity and subjective experience will vary, including the degree to which the shock poses a risk of harm to the individual. For this reason, as discussed here and in Response 18, the subjectivity of the pain and variability of the shock intensity elevate FDA’s concern regarding the risk of pain and other harms in that they make it difficult to predict the impact that a particular shock will have on a particular individual at a particular time.

Several Panel members expressed concerns regarding the difficulties and lack of understanding regarding dosing (shock intensity) and variability in individual pain thresholds from both safety and effectiveness standpoints (see, e.g., Ref. 15 at 50, 89, 137, 296, 302, 326, 349). Further, although all ESDs covered by this ban present the risk of pain, some ESDs, such as JRC’s GED–4, which delivers more than triple the maximum electrical current of the GED–1, present an even higher risk of pain than others. The increased current means the device is likely to cause more pain than lower current ESDs notwithstanding the element of subjectivity in the experience of pain. In addition, this physical pain may lead to psychological trauma, discussed further in Response 18.

FDA acknowledges that, in 1994, FDA found an earlier model of one of JRC’s GED devices substantially equivalent to predicate aversive conditioning devices. Regardless of what data JRC may have submitted at that time or how FDA evaluated it for substantial equivalence to predicate devices in the context of a 510(k)—i.e., a premarket notification submission under section 510(k) of the FD&C Act (21 U.S.C. 360(k))—we are not bound by such in a banning proceeding under section 516 of the FD&C Act. To ban a device, we consider

all available data and information. The past 25 years since the clearance of that GED have yielded valuable data, analyses, and experience with ESDs for SIB or AB, as well as advancements in science and medicine. These data and information have improved our understanding of the risks posed by this type of device, including the risk of pain, as well as the diagnosis of, and treatment options for, patients that exhibit SIB or AB.

As for other physical harms, FDA disagrees that the shock strength of ESDs is not capable of producing other physical harms. In our analysis of physical risks in the proposed rule, we explained that the literature contains reports of tissue damage that ranged from burns to bruises. As discussed further in the next comment response, the literature is supported by evidence contained in numerous comments to the docket, including those from NYSED, the U.S. Department of Justice, and a former employee of JRC. Other risks that FDA identified in the scientific literature include increased frequency or bursts of self-injury and errant shocks from device misapplication or failure. In addition, FDA considered risks identified through other sources, which provide further support for the physical risks reported in the literature and indicate that ESDs are associated with additional physical risks of neuropathy and (potentially less seriously) injuries from falling (see Ref. 15 at 312, summarizing additions to list of risks).

In sum, although pain has an element of subjectivity, pain correlates roughly with the maximum electrical current output by the device. The device is intended to cause pain and is capable of causing other physical injuries under certain conditions. However, the variability of those conditions as well as the subjective element in the experience of pain make it difficult to minimize the risks of any given shock or series of shocks. Experts on the Panel echoed these concerns.

(Comment 15) One comment specifically objects to FDA’s characterization of six references reporting on tissue damage or burns.

(Response) FDA has reviewed the references and agrees that two do not support the original analysis of tissue damage and burns, and we have determined that the literature cited does not by itself establish the risk of tissue damage or skin burns attributable to the use of ESDs. However, the other references together with other sources do support these risks, as we explain in the following paragraphs. Further, based on the new analysis, FDA’s ultimate conclusion that the risk presented by

the device is unreasonable and substantial did not change.

We stated in the proposed rule that the literature contains many reports of tissue damage or burns from ESDs and cited several references to that effect. However, one reference that we cited did not report tissue damage or burns, and it stated that “there was little to suggest the development of adverse side-effects” (Ref. 16). Considering the study was conducted in 1975 and did not systematically observe or record AEs, and given that it studied only two subjects, the change to our evaluation of the benefit-risk profile is minimal. It does not affect our overall conclusion with respect to the substantial and unreasonable risks.

Another reference that we cited for the risk of tissue damage, Ref. 17, did not report tissue damage as a direct result of individual shocks applied to the skin. Instead, the reference discusses the possibility that individuals may, after extended device application, manifest SIB that eventually results in tissue damage. Although we no longer consider this reference to support the risks of skin burns or tissue damage as a direct result of ESD use, given the multiple other references that support these risks, FDA continues to find that a risk of using ESDs is skin burns or tissue damage. In our re-evaluation, we note that this source did not systematically observe and record AEs, that its conclusion about effectiveness was tentative (“might be”), and that it had a small sample size (eight individuals) with high variability. As such, the re-evaluation does not change our overall conclusion with respect to the substantial and unreasonable risks of ESDs.

The comment also criticizes FDA’s characterization of Ref. 18 as providing a report of burns to the single individual it studied. The comment notes that the device was not intended for human use and that its replacement, a device intended for human use, did not cause burns because the electrodes were placed directly on the skin. Although placing electrodes directly on the skin would reduce the likelihood of electrical arcing and the risk of skin burns from arcing, this does not eliminate the risk of burns more generally; in the proposed rule, we did not attribute the risk of burns solely to electrical arcing. As we stated in the proposed rule, Dr. James Eason, a biomedical engineer, opined that ESDs intended for human use, such as the SIBIS, GED–1, and GED–4, are capable of causing superficial skin burns under certain circumstances (81 FR 24386 at 24396). Similarly, a member of the

Panel noted that a 20-milliamperes shock can cause a first-degree burn (Ref. 15 at 140). Further, the type of device that is banned could include technology in which the electrodes are not placed on the skin and arcing occurs. Thus, whether the electrodes are attached directly to the skin or not, we continue to believe burns or other tissue damage are risks posed by ESDs for SIB or AB.

The comment also takes issue with FDA’s interpretation of Ref. 19, stating that reddened areas occurred from wearing the device and not from the shocks themselves. FDA considers reddened areas from device use to be evidence of tissue damage, although FDA considers Ref. 19 to be evidence of a minor harm. During an exchange at the Panel Meeting, some question arose over whether such damage is erythema or a first-degree burn (see Ref. 15 at 140). A representative of JRC explained that he did not know but had been told by dermatologists that it was erythema (see Ref. 15 at 141). However, he later added “[w]ell, that depends on your definition. Is this a burn or not?” and again referred to dermatologists’ statements (Ref. 15 at 141). FDA interprets these statements to mean that some injury to the skin, although it may be minor, has occurred from use of the device, and we believe that referring to such an injury as “tissue damage,” as we did in the proposed rule, is accurate.

Similarly, the comment emphasizes that the tissue damage from a SIBIS reported in Ref. 20 resembled a bruise rather than a burn. According to the reference, this mark lasted about a week before it disappeared. The comment also presents a quotation from Ref. 7 that the use of GEDs resulted only in “an occasional temporary discoloration of the surface of the skin that cleared up within a few minutes or a few days.” As before, regardless of whether the bruise-like mark and discolorations which could last for days were burns or bruises, we consider both to be tissue damage and described them accurately in the proposed rule as temporary. As such, FDA continues to identify tissue damage or skin burns as risks.

The risk of tissue damage or skin burns is supported by additional sources. As discussed in the proposed rule, FDA reviewed complaints made to the Massachusetts Disabled Persons Protection Committee related to the use of ESDs for SIB or AB (Ref. 21, incident #49037). In 2007, the Massachusetts Department of Early Education and Care (DEEC) conducted an investigation of JRC’s Stoughton Residence, where ESDs were used (Ref. 21). According to the Investigation Report, an individual reported waking up because his

roommate was screaming; his roommate had been asleep but was shocked by a GED, waking him and causing him to scream. JRC staff reported that “the skin was off of the area” of the leg where GED shocks had been applied, that the GED was removed from the leg “because the area . . . was too bad to keep the device,” and either the individual who received the shocks or the staff believed a stage 2 ulcer had developed (Ref. 21).

In addition, the NYSED conducted an onsite review of JRC’s behavior intervention program and “witnessed staff rotating GED electrodes on individuals’ bodies at regular intervals to ‘prevent burns that may result from repeated application of the shock to the same contact point.’ ” (See Ref. 22, summarized in the proposed rule, 81 FR 24386 at 24397.) Further, NYSED, in a comment submitted to the Panel Meeting, stated that they “received numerous reports of students who have incurred physical injuries (burns, reddened marks on their skin) as a result of being shocked,” (Ref. 23). NYSED reviewers also noted that school nurses monitor the individuals’ skin for burns (Ref. 22).

We also have reports of burns from individuals formerly at JRC as well as their parents. At the Panel Meeting, one such parent described burns their child acquired from ESD applications (Ref. 15 at 203). The individuals who were interviewed by FDA staff shared their negative experiences at JRC and similarly reported burns that they attributed to the use of ESDs (see Ref. 15 at 62–63, summarizing experiences). In sum, the literature, Panel Meeting proceedings, NYSED report, and individual anecdotal reports support the conclusion that ESDs present the risk of tissue damage, including skin burns.

(Comment 16) Commenters point out instances in the proposed rule in which FDA misattributed or misstated information from certain sources regarding certain risks.

(Response) FDA has reviewed the references, and we acknowledge some misattributions and misstatements.

We have revised our analysis as follows:

(a) We stated that one risk is the intensification of an undesirable behavior known as self-restraint. We attributed this information, in part, to Ref. 24; however, this reference does not provide support for the stated observation. Nonetheless, we cited another reference for this observation, and FDA continues to regard the intensification of self-restraint as a risk from the use of ESDs for SIB or AB (Ref. 17).

(b) We stated that an adverse outcome from ESD use for SIB or AB is the manifestation of napkin-tearing, an undesirable behavior. However, upon review, we do not regard napkin-tearing as an adverse outcome. Because the risk to self and others from napkin-tearing is minimal, the removal of this adverse outcome from our evaluation of the benefit-risk profile is of little consequence and does not affect the overall conclusion with respect to the substantial and unreasonable risks of illness or injury from the use of ESDs for SIB or AB.

(c) We stated that an adverse outcome from ESD use for SIB or AB is an increase in affection seeking. However, the study indicates that affection seeking replaced “pathological behaviors,” meaning affection seeking was a relatively desirable effect (Ref. 25). This affects our evaluation of the benefit-risk profile in that it updates an incorrectly identified risk to be a potential benefit, meaning the profile is slightly more favorable than previously appreciated. However, considering the small magnitude of this change, and that this study was conducted in 1965 and did not systematically observe or record AEs, this change does not affect our overall conclusion with respect to the substantial and unreasonable risks.

(d) We stated that, except for the harms described elsewhere in the proposed rule, JRC maintains that it “has not found any side effects associated with aversive conditioning” and “there are no confirmed reports or confirmed medical evidence that patients have any negative psychological side effects related to any discomfort experienced due to therapy with the proper use of the GED devices.” JRC has clarified that the full sentence reads: “JRC has not found any side effects associated with aversive conditioning except the occasional discoloration of the skin that disappears within an hour to a few days and some brief, temporary anxiety just prior to the delivery of the application.” Because we included all of the information in this sentence elsewhere in the proposed rule, this does not affect our evaluation of the benefit-risk profile or our overall conclusion with respect to the substantial and unreasonable risks.

(Comment 17) Some comments question the validity of FDA’s attribution of certain risks of implantable cardioverter defibrillators (ICDs) to ESDs. One such comment argues that risks must be considered based on the intended patient population and the purposes of the device, and there is no basis for attributing the risks of ICDs to ESDs for

SIB or AB. The comment also notes that the scientific literature does not compare ESDs for SIB or AB to ICDs.

(Response) FDA agrees that the differences between ESDs and ICDs, including intended uses, prevent FDA from drawing meaningful conclusions from ICDs about the risks of ESDs. In the proposed rule, we expressly observed that the devices have drastically different intended uses, patient populations, benefit-risk profiles, and states of the art of treatments for the intended patient populations. Upon further consideration, with stakeholder input, we have determined that comparison of these devices is not enlightening for the purposes of this final rule and have updated our assessment of the risk profile of ESDs accordingly.

Despite this update, FDA has determined that risks of illness or injury posed by the use of ESDs for SIB or AB are substantial and unreasonable. In the proposed rule, FDA used the comparison with ICDs to support the risks of posttraumatic reactions, up to and including PTSD, based on the pain and corresponding distress of potential future shocks. FDA made a comparison on the basis that each device delivers an electric shock to an individual that is out of the individual’s control, occurs multiple times, and is generally perceived as surprising and painful or unpleasant. As such, our comparison was narrow, limited to the particulars of such a stimulus, and yielded additional support for observations already made based on consideration of ESDs themselves. The removal of the narrow comparison from our assessment therefore does not remove the basis for identifying such risks even though it removes some support based on a device type comparison.

With regard to ESDs (considered on their own), FDA identified distress of potential future shocks in particular as a trauma that people subject to ESDs may experience, meaning that the ongoing application of ESDs compounds the risk. Although we are no longer drawing support from the narrow comparison to ICDs for this premise, we have elsewhere explained our further consideration of the evidence supporting posttraumatic reactions, up to and including PTSD. Comments to the docket supported that people subject to ESDs experience this trauma. To summarize very briefly, further consideration of that data and information has bolstered our conclusion that the repeated application of a painful stimulus such as that from an ESD, in particular when it is not within the recipient’s control,

contributes to and escalates the risk of developing acute and/or chronic posttraumatic reactions. (See Response 18 for more detail.) Thus, we believe the evidence for the risks of such reactions is as strong as that discussed in the proposed rule.

Further, as explained in Response 13 and elsewhere, we believe that the proposed rule understated the harm of pain. As JRC acknowledges, the shock from an ESD is intended to be painful, and the scientific literature and statements from individuals who were subject to ESDs (as well as others who have tested ESDs on themselves) indicate that the pain from such shocks is severe, and it causes distress and fear. We believe that this evidence bolsters our previous findings and suggests the pain from the device is a reasonable basis to find support for distress of future shocks from ESDs, potentially leading to posttraumatic reactions (see Response 18).

In sum, upon further consideration, we have removed the narrow comparison to ICDs from our assessment of risks, but information and data from other sources confirms and bolsters the risks of posttraumatic reactions, up to and including PTSD, based on the pain and corresponding distress of potential future shocks. As such, our overall conclusion has not changed with regard to the substantial and unreasonable risks of ESDs used for SIB or AB.

(Comment 18) A comment questions whether references support FDA’s statements about psychological trauma, namely that: (1) When the recipient does not have control over the shocks and has previously received multiple such shocks, psychological trauma such as an anxiety or panic reaction can result even when the strength is relatively modest (see Ref. 26) and (2) a series of less traumatic events can cause the development of stress disorders such as PTSD (see Ref. 27; see also Ref. 26). The comment takes issue with FDA’s interpretation of the references, particularly regarding current diagnostic criteria for PTSD, the nature of a Criterion A event (one of the diagnostic criteria in DSM–5), and the evidence regarding a dose-response relationship between traumatic events and manifestations of PTSD.

(Response) FDA disagrees. As discussed in Response 13, based on information submitted in comments, FDA believes it understated the harm of pain in the proposed rule. For example, one clinician, Dr. Edwin Mikkelsen, testified in the Massachusetts hearing that the shock was excruciatingly painful and should not be used on humans, that it was unconscionable,

and that it prompted the doctor to resign from the Level III certification team (Ref. 14, day 7 at 161–63, 193–94). Another clinician, Dr. James McCracken, stated that “[t]his shock is intense. It is not a simple tickle or a buzz. It is frightening.” (Ref. 14, day 9 at 158.) The doctor went on to describe it as extremely painful, causing involuntary movement, and that it raised very strong ethical concerns (Ref. 14, day 9 at 82, 86). Yet another clinician, Dr. Jeffrey Geller, described the shocks as quite painful, “worse than a bee sting,” “much worse than a hard pinch,” and like a “bulging and a ruptured disc,” causing “writhing gyrations” (Ref. 14, day 21 at 81–83). Dr. Jennifer Zarcone, another clinician, described the shocks as “very painful, and I got very upset. It’s probably the most painful thing I’ve ever experienced.” (Ref. 14, day 13 at 217–18). In short, FDA does not believe that the pain from the shocks from ESDs currently in use is actually modest for the individuals subject to them. The intensity of pain from the shocks suggests that individuals are more likely to experience trauma that may lead to psychological symptoms.

Further, as discussed in the paragraphs that follow, regardless of how a single shock is perceived by a particular shock recipient, FDA believes that a series of shocks can be traumatic to the individual and give rise to psychological harms, including anxiety, stress reactions, learned helplessness, acute stress disorder, and even PTSD. When the recipient does not have control over the shocks and has previously received multiple such shocks, the risk may be yet greater, especially in that learned helplessness may be more likely. Finally, the vulnerability of this patient population and the circumstances of the event, including the interpersonal nature of the trauma, the ongoing nature of the shocks, and the fact that the device is attached to the recipient’s body, may further increase the risk of psychological harms.

The Diagnostic and Statistical Manual of Mental Disorders (DSM) includes diagnostic criteria for PTSD; Criterion A regards the stressor event to which an individual is exposed. The current edition, DSM–5, originally published in 2013, incorporates a broader definition of a Criterion A event than previous editions: The person must be exposed to death, threatened death, actual or threatened serious injury, or threatened sexual violence through direct exposure, witnessing the trauma, learning that a relative or close friend was exposed to a trauma, or indirect exposure to

aversive details, usually in the course of professional duties.

In criticizing FDA’s explanation, the comment has apparently misunderstood both FDA’s statements and the previously cited references with respect to how the diagnostic criteria for PTSD have evolved, and the comment mischaracterizes the necessity of a single Criterion A event and the literature’s findings. The criteria have evolved such that a diagnosis of PTSD may be based on a series of events rather than a single, discrete event. Even before the DSM update, the literature had found that people exhibited the symptoms of PTSD even when a single, discrete event did not appear to cause the symptoms. The explanation of the revised diagnostic criteria, from the DSM–IV to the DSM–5, makes clear that PTSD may develop from threatened (not only actual) harm or from a series of traumatic events (not only a single, discrete event).

Thus, shocks that individually may appear modestly stressful to an observer could constitute a Criterion A stressor under the DSM–5 when multiple such shocks are administered, even though they may not have met Criterion A under prior iterations of the DSM. This is especially true when the recipient is experiencing additional vulnerabilities or circumstances discussed later in this response (e.g., the interpersonal nature of the shock delivery, the attachment of the device serving as a constant threat of future shocks). This change in Criterion A relates to the argument in Ref. 26, that the previous version of Criterion A, which contemplated a single, discrete, highly traumatic event, did not in fact serve its intended gatekeeper function and was not a useful criterion because people still manifested the symptoms of PTSD without such an event as it was then defined. The revisions to the diagnostic Criterion A for PTSD were intended to bolster its effectiveness as a gatekeeper criterion by more comprehensively capturing the kinds of events that can result in PTSD symptomatology. Thus, although the commenter states that Ref. 26 “comes to opposite conclusions,” the conclusions of Ref. 26 and the parallel evolution of the DSM clearly support FDA’s determination that a series of traumatic events, even those events that may appear modestly stressful to observers, can give rise to stress disorders, including PTSD.

Turning to the issue of dose response, as the comment points out, Ref. 26 empirically reviews evidence and ultimately questions the then-current paradigm for diagnosing PTSD, based on what the reference calls “core

assumptions,” including that PTSD has a specific etiology and that the severity of the trauma has a strong dose-response relationship to the severity of PTSD. The authors review the evidence regarding each of these assumptions and conclude that the assumptions did not adequately account for the manifestation of many cases of PTSD, implying that the assumptions were wrong in some way.

We agree with the commenter and the authors that the dose-response relationship between the severity of the trauma and the stress disorder is weak, meaning that the severity of the symptoms or resulting disorder may not correspond with the severity of the trauma. The authors also find that people exhibited the full symptomatology of PTSD even if the trauma that caused the symptoms did not satisfy the then-current (pre-DSM–5) Criterion A. While the comment agrees with these authors and FDA that there is a weak or nonexistent dose-response relationship, it misunderstands the implication of this, which is that severe symptoms may manifest even if the trauma is not severe.

In an apparent attempt to alleviate concerns relating to psychological risks from a painful shock, the commenter elsewhere states that electrical stimulation is easily measured objectively, and implies that a psychologically harmless level can be set. First, as discussed earlier, due to the complexity of the interactions between different output settings (e.g., pulse width, frequency, electrode size) and inter-individual variability in shock perception, it is difficult to define a cutoff stimulation for pain or trauma. The Panel understood this and was very concerned about the impact this variability could have. Most importantly, individuals who are subject to ESDs are repeatedly exposed to a painful stimulus, and several individuals have expressed that they were anxious and/or fearful about future shocks. Further, because the dose-response relationship between a trauma and the severity of resulting psychological symptoms is weak, it would be even more difficult to use electrical parameters to predict whether any eventual psychological symptoms will be mild or nonexistent, and FDA is unaware of data demonstrating such. (See also FDA’s discussion in the proposed rule about how an individual’s perception of the trauma is not reliably predicted by the electrical parameters, 81 FR 24386 at 24393–24394.) Regardless of the ability to draw such a line, the GED devices currently in use pose all of the physical and

psychological risks discussed in this rule.

The comment also apparently misunderstands FDA's reference to an article that in turn refers to an earlier edition of the DSM. The DSM-III-R, originally published in 1987, specified that the person must have witnessed or experienced a serious threat to life or physical well-being, but the current DSM-5 contemplates a wider spectrum of events that may be traumatic and other, more indirect ways to experience traumatic events, thereby broadening Criterion A. Specifically, the current version of Criterion A in the DSM-5 also allows for "threatened" traumas, meaning that the event has not actually occurred. Not only does an ESD patient experience the trauma of a severe pain, which can be a Criterion A event, but the device is attached to the patient's body, constantly threatening additional trauma. FDA's reference to the article helps to illustrate the evolution of the diagnostic criteria and supports the risk of developing PTSD symptoms. In short, a contemporary understanding of trauma associated with PTSD or its symptomatology supports that these are risks of receiving shocks from the devices.

Indeed, this commenter elsewhere quotes the American Psychiatric Association (APA), the publisher of the DSM, which explicitly compared the DSM-5 to the DSM-IV: "Compared to DSM-IV, the diagnostic criteria for DSM-5 draw a clearer line when detailing what constitutes a traumatic event. Sexual assault is specifically included, for example, as is a recurring exposure that could apply to police officers or first responders" (Ref. 28). The APA has explained that the current diagnostic criteria now accommodate trauma stemming from repetition, and the criteria now focus more on the symptoms the individual displays rather than describing the individual's subjective response to a given event. Criterion A also includes witnessing a trauma. Thus, even an individual who witnesses another receive an ESD shock is potentially at risk for developing acute stress disorder or PTSD from the experience, particularly if the witness has been sensitized by the experience of having received an ESD shock themselves. Indeed, Panel members expressed great concern about the impact on staff of using this device (see Ref. 15 at 310); this concern is heightened for individuals subject to ESDs who witness traumas of others.

The literature, including Ref. 26, discusses additional factors in the development of PTSD symptoms, such as individual vulnerabilities and

resilience, and the literature distinguishes the manifestation of anxiety or stress from the development of a disorder in light of such characteristics. Psychological traumas, regardless of whether the results are characterized and diagnosed as PTSD, are more likely for vulnerable individuals, depend on the circumstances of the event, and can be more severe without effective emotional support afterward (see Ref. 26). In the case of ESDs, the individuals subject to them are generally more vulnerable because of their cognitive impairments and, in many cases, comorbid conditions. Many individuals subject to ESDs have an impaired ability to associate cause and effect, which, as we noted in the proposed rule, increases the risk of psychological harms (see 81 FR 24386 at 24395). Such vulnerable individuals are particularly susceptible to the risk of learned helplessness. Despite this, JRC does not monitor for or assess PTSD or other stress disorder symptomatology according to its records, meaning individuals are less likely to receive adequate emotional support.

While the commenter did not specifically address the portion of FDA's statement regarding the lack of control over multiple shocks, this is an additional risk factor. The risk of psychological trauma may be greater when the recipient does not have control over the shocks and has previously received multiple shocks, because learned helplessness may be more likely. An individual's inability to control receiving an aversive stimulus such as a shock from an ESD is often linked to learned helplessness (see, e.g., Ref. 15 at 311, summarizing mentions of learned helplessness). Further, device malfunctions and staff's inappropriate delivery of shocks result in many noncontingent shocks being received (Ref. 15 at 59 (summarizing 53 filed complaints), 310 (concerning JRC staff)). As a Panel member stated, "there are multiple episodes of non-contingent infliction, including malfunction of the device." (Ref. 15 at 310.) The risk of psychological harm increases if the shocks are delivered noncontingently or if the individual subject to the ESD is unable to understand that the shock is related to undesirable behavior. Panel members explained that this is the perfect paradigm for learned helplessness (Ref. 15 at 304).

We note that, in addition to the relationship among vulnerabilities, noncontingent delivery of shocks and psychological risks, noncontingent delivery also undermines the effectiveness of the punishment

paradigm for ESDs. ESDs are intended to accomplish behavior modification through punishment. This depends on consistent, contingent delivery of shocks. Correspondingly, it also depends on the ability of the individual to associate cause and effect, *i.e.*, recognize the contingency. If shocks are delivered noncontingently, or the individual does not perceive the contingency, the treatment paradigm and potential effectiveness of the device are undermined.

Further, circumstances surrounding the application of shocks may amplify the harms. In particular, the DSM-5 states that PTSD "may be especially severe or long-lasting when the stressor is interpersonal and intentional (*e.g.*, torture, sexual violence)," (Ref. 29 at 274). An ESD shock is interpersonal because it comes from a person the recipient identifies as a caregiver, the shock is intentional because the monitor must activate the device, and the shocks occur repeatedly over a long period of time. Repeated ESD shocks, because of their interpersonal nature, may therefore precipitate especially severe or long-lasting symptoms.

Based on other evidence discussed in the proposed rule and received in comment responses, ESD use can be linked with DSM-5 criteria for PTSD, most clearly including Criterion A, Criterion B intrusion symptoms (intrusive distressing memories), Criterion C symptoms (persistent avoidance of stimuli associated with the traumatic event), and Criterion D symptoms (negative alterations in cognition and mood). While there are eight criteria in the DSM-5 that need to be met for a diagnosis of PTSD in a particular patient, the evidence in the record corresponding with some of these criteria is sufficient for FDA to conclude that ESDs for SIB or AB pose a risk of developing PTSD; actual occurrence of a particular harm is not necessary for FDA to determine a device presents a risk of that harm. Further, lack of information regarding some of the criteria may be due to poor recordkeeping, clinical oversight, and training of personnel at JRC to identify safety and effectiveness outcomes.

In addition to being part of a diagnosis of PTSD, the PTSD symptoms for which we have evidence are also harms on their own. For example, FDA has evidence that recipients of ESD shocks have experienced nightmares, flashbacks, avoidance, startle, hypervigilance and reexperiencing symptoms, and even the JRC training manual indicates that the following symptoms of PTSD should be monitored for: nightmares, flashbacks, avoidance,

startle, and hypervigilance. One patient reported nightmares, flashbacks, and re-experiencing symptoms as a result of the ESD administration (Ref. 15 at 63). The Panel discussed that various symptoms of PTSD, including nightmares, flashbacks, emotional distress, and intrusive thoughts, were found in individuals who have been subject to ESD shocks, although no systematic psychiatric assessment using DSM criteria was conducted for PTSD (see Ref. 15 at 154, summarizing such symptoms in people subject to ESDs). Additionally, of 53 complaints filed from 1993–2013 regarding ESD with the Massachusetts Disabled Persons Protection Committee (DPPC) that FDA reviewed, negative emotional reactions and PTSD were reported as AEs (Ref. 15 at 59). From 2010 to 2013, FDA officials were contacted by, and met with, representatives from various national disability organizations. These organizations reported at least four case reports of psychological trauma and PTSD symptoms, and stressed that alternative treatments, such as positive environmental and reinforcement strategies, have been developed and are generally successful for severe and refractory self-injury (see Ref. 5 at 72; see also Ref. 15 at 59).

If shock recipients develop PTSD symptoms, they may be more severely impacted by future shocks because they could have “heightened sensitivity to potential threats, including ones that are related to the traumatic experience” (Ref. 30 at 275). “Symptom recurrence and intensification may occur in response to reminders of the original trauma, ongoing life stressors, or newly experienced traumatic events” (Ref. 30 at 277). Reminders of past shocks, for example, seeing the staff member(s) who administered the shocks or seeing others suffering the same trauma, may contribute to re-traumatization. Significantly, the ESD itself remains attached to the individual’s body, presenting a near-constant reminder of past trauma, so FDA believes there is a meaningful potential for re-traumatization subsequent to painful and traumatic stimuli such as the shocks delivered by ESDs. The testimony during the Massachusetts hearing reflected such concerns. Dr. McCracken emphasized the heightened risk of trauma from exposing a member of a vulnerable patient population to continual, painful shocks over a period of years, in many cases several years (Ref. 14, day 9 at 158–59).

FDA’s review of JRC’s records did not find evidence that JRC monitors for or asks about PTSD, including assessment of the cardinal symptoms of PTSD.

Given the literature, the testimony about ESDs specifically, and the fact that JRC does not monitor for such harms, FDA disagrees with JRC’s assertions that ESDs would not cause PTSD or PTSD symptoms, among other psychological harms. In short, the evidence indicates that shocks from an ESD can cause PTSD or several of its symptoms, and once the symptoms arise, recipients may be even more susceptible to harms from future shocks.

In sum, the literature on PTSD has evolved to recognize situations like the repeated use of ESDs, where a series of events together may be traumatic enough for some individuals to develop posttraumatic reactions, including acute stress disorder, PTSD symptomatology, and PTSD. As we explained in the proposed rule, psychological risks also include anxiety, panic reactions, learned helplessness, and other stress disorders (see, e.g., 81 FR 24386 at 24393 to 24394). Manifestations of these harms may contribute to a PTSD diagnosis, but they are also harms on their own. Individuals subject to ESDs for SIB or AB also have vulnerabilities that tend to increase the risks of experiencing psychological harms. Based on the literature, modern diagnostic criteria, and expert opinion, FDA has determined that ESDs used for SIB or AB pose the risk of causing those psychological harms.

(Comment 19) One comment states that the pseudocatatonic sitdown reported in one article and described as an adverse event by FDA was an act of self-restraint and was an improvement over previous behaviors.

(Response) FDA disagrees with the comment. Entrance into a pseudocatatonic state is a risk posed by the use of ESDs. The authors of the reference proposed that the pseudocatatonic behavior was a self-protective response to avoid punishment: They “surmised that this global muscular ‘freezing’ or ‘melting’ provided ‘insurance’ for the patient, preventing her from striking out and consequently being punished for doing so” (Ref. 31). The patient became temporarily unresponsive, even upon receiving affection from caregivers. Thus, even assuming the authors were correct that the pseudocatatonic state was “insurance” against striking out, this does not mean that the behavior was not an adverse effect or risk. Particularly in the case of certain aggressive, non-self-injurious behavior, this change in behavior is not necessarily an improvement for the patient. Replacing aggressive behaviors such as curses, threats, or striking out against others with a lack of all

responsiveness is not necessarily an improvement in the patient’s wellbeing. Indeed, a Panel member made clear that generalized behavior suppression is a risk and occurs, i.e., “when experiencing a great deal of punishment, some people just stop behaving in general” (Ref. 15 at 305; see also id. at 312). This is also concerning because less-invasive behavioral techniques such as those that are within the state of the art would not provoke responses such as a pseudocatatonic state. FDA is not persuaded that more acceptable behavior from an outsider’s perspective equates to improved wellbeing for the patient. FDA continues to regard generalized behavioral suppression, such as pseudocatatonic reactions, as a risk of ESDs used for SIB or AB.

(Comment 20) One comment states that crying decreased after use of aversives in one instance where FDA claims that crying increased, citing Ref. 32.

(Response) FDA disagrees. Although Ref. 32 reports decreased crying during one phase of the study involving contingent shock, crying increased in the final treatment phase, which also involved contingent shock (Ref. 32 at 621). In addition, other studies report crying as an AE from ESDs for SIB or AB, including increases in crying during later sessions (see, e.g., Ref. 33 at 117). Because crying, which can be indicative of trauma, did in fact increase in the cited reference as well as other references, FDA continues to consider increased crying as an AE associated with the use of ESDs for SIB or AB.

(Comment 21) One comment claims FDA incorrectly cites Ref. 34 to support the risk that ESDs cause temporary or long-term increases in symptoms and frequency of SIB. The comment alleges that this is a “complete misstatement” because in fact the authors reported a decrease in target behaviors to zero.

(Response) Regarding a temporary or long-term increase in symptoms, FDA disagrees. While the article cited states that “[h]owever by the fifth day of Phase 1 treatment, self-mutilative behaviors were reduced to zero, and emotionality had returned to pretreatment levels,” the article concludes by noting that the subject had “become more incontinent during waking hours since termination of the treatment program” (Ref. 34). Moreover, the subject’s initial reaction “was an increase in emotionality and in frequency of self-mutilative behaviors” (Ref. 34). Accordingly, FDA believes the commenter is incorrect.

(Comment 22) One comment argues that FDA misrepresented the findings of Ref. 35 regarding the risk of undesirable

replacement behavior, given the statement in the article: "Our experience suggests that once most SIB has been eliminated, especially if it was deliberately replaced by new, desirable behaviors, favorable qualitative changes often took place in the behavior of the patients."

(Response) FDA disagrees. Although the article does state that favorable changes *often* took place in the patients "once most SIB had been eliminated, especially if it was deliberately replaced by desirable behaviors," (Ref. 35, emphasis added), this does not mean favorable changes usually or always took place, or that most SIB was often or usually eliminated, or, most importantly, that it was often or usually replaced by desirable behaviors. Indeed, the article explains that, at one of the study sites where skin shock was used, the positive effects were temporary, and SIB returned if shocks were delivered by a different staff member or in a different room (Ref. 35). The authors observed, "[o]ccasionally, when one type of SIB is reduced, another would appear in its place," and, given the likelihood of reinforcement of negative behaviors, "the probability that a replacement behavior will be undesirable is quite high" (Ref. 35).

In addition, one of the commenter's own references states that positive behaviors that were not the targeted behavior can be modified during treatment (Ref. 36). This information supports FDA's statement regarding undesirable replacement behavior as a risk posed by ESDs for SIB or AB.

(Comment 23) One comment states that FDA misrepresented references reporting hostility and retaliation as adverse events. The commenter views hostility and retaliation as part of those patients' preexisting behavioral history.

(Response) Upon further consideration, FDA believes that additional context will help inform the likelihood of the risk of hostility and retaliation. In Refs. 29 and 31, the patients' hostility and aggression were part of the patients' clinical presentation. In Ref. 29, the researchers state "it is difficult to know whether [the patient's] infrequent attacks represent retaliation for the punishment," *i.e.*, retaliation for the aversive stimulus used to reduce AB. Nevertheless, "viewed against the long history of this kind of behavior" and "the long period of time (containing many positive reinforcements) between the infrequent aversive stimuli and the assaultive incidents," they doubt the aversive stimulus provoked retaliation. Thus, the researchers considered hostility and retaliation hypothetical

risks of the use of aversive stimuli but deemed the risks doubtful in light of additional information.

FDA cited Ref. 31 to support similar risks, specifically surrogate retaliation, threats, and warnings. However, as the researchers targeted certain aggressive behaviors, the patient progressed through "petit" aggressions," less severe replacement behaviors, some of which the authors describe as "surrogate retaliation." This reference therefore indicates that surrogate retaliation and threats to others, while undesirable, were improvements upon the patient's state prior to application of skin shocks.

Taken together, in these researchers' opinions, these hostile or retaliatory behaviors are not AEs from the use of ESDs for AB. However, the commenter's own literature submissions support the risk of the creation of hostility:

- Ref. 37, considerable hostility regarding the proceedings;
- Ref. 38, aggressiveness, anger, and disgust;
- Ref. 39, risk of elicited and operant aggression; and
- Ref. 40, negative reactions to authority figures.

FDA is updating its risk analysis to reflect that hostile or retaliatory behaviors in response to the use of ESDs may be a risk but is not well supported. In particular, these behaviors may be difficult to distinguish from preexisting aggression. However, this does not change our overall conclusion regarding the substantial and unreasonable risk of illness or injury from the use of ESDs for SIB or AB, which FDA reaches based on our analysis of the other risks posed by ESDs for SIB or AB such as posttraumatic reactions, pain, and other injuries, much of which has been bolstered based on comments to the proposed rule.

(Comment 24) A comment questions FDA's scientific basis for inferring that seizures or heart palpitations may result from the application of ESDs.

(Response) FDA agrees that the scientific literature does not support the link between the application of ESDs and seizures. Accordingly, FDA noted in the proposed rule that the sources for such information were individuals who attributed their seizures to the use of ESDs as well as advocacy groups that stated that the shock could trigger seizures. We then explained, on the basis of such statements, that ESDs may pose additional risks including seizures. Although this commenter explains that current would have to be applied across the brain to induce seizures, FDA notes that the biochemical pathways that contribute to seizures are not well understood. As such and given the

dearth of research on the effects of ESDs, FDA continues to regard seizures as a possible additional risk, but we agree that this is not a well-established risk. Since we weighed the evidence in part according to its source and the degree of support in the scientific literature, we did not accord this information significant weight, and it does not significantly affect our evaluation of the benefit-risk profile of ESDs for SIB or AB.

With regard to the evidence of the risk of heart palpitations, FDA believes the evidence is somewhat stronger but acknowledges the risk also has not been well studied. The commenter describes the manner in which electrodes would have to be placed on the skin in order to cause palpitations as a direct result of electric current flowing through the heart. He states that, because ESD electrodes are not arranged in that way, individuals subject to ESDs should not experience palpitations. In contrast, an individual who was subject to ESDs and an expert in this field have opined that the use of one model of ESD, a GED, presents a risk of heart palpitations to the patient (Ref. 15 at 63; Ref. 41, attachment 2).

We note that people who manifest SIB or AB may have conditions or take medications that increase their predisposition for palpitations; however, the relationship between such a predisposition and the risk of this harm from the application of ESDs is speculative. As with the potential additional risk of seizures, the reports are anecdotal, so we did not accord them significant weight, and they do not significantly affect our evaluation of the benefit-risk profile.

(Comment 25) One comment objects to FDA's reliance on JRC's policy document listing possible collateral effects of ESDs because this document was created in response to a requirement from the NYSED through Corrective Action Requests to include a discussion of the collateral effects of aversive interventions in its policies, and there is no evidence ESDs caused any of these collateral effects.

(Response) FDA disagrees. The discussion of possible AEs that JRC included in its documents is consistent with the literature and NYSED's reports. It is also consistent with information identified by and submitted to FDA by individuals formerly at JRC and their parents. Specifically, NYSED received reports of AEs, which NYSED refers to as collateral effects, from the use of these devices, such as increases in aggression and increases in escape behaviors or emotional reactions. Also included were "numerous reports of

students who have incurred physical injuries (burns, reddened marks on their skin) as a result of being shocked and for whom parents and students themselves have reported short-term and long-term trauma effects as a result of use of such devices or watching other students being shocked (e.g., loss of hair, loss of appetite, suicidal ideation),” (see Ref. 22).

In addition, based on its site visit, the NYSED criticized JRC for inadequate monitoring for AEs, which partially precipitated the Corrective Action Requests. Without adequate monitoring, JRC’s statement is not persuasive when it says that “no evidence” shows the use of ESDs caused the “collateral effects.” Adequate monitoring is necessary to instill confidence in such claims. Given the reasons NYSED required the statements, the consistency with the literature and anecdotal reports, and the fact that JRC ultimately included the statements in its documents, we continue to regard this information as evidence of risks.

(Comment 26) A comment questions the validity of FDA’s concerns regarding AEs and underreporting because the commenter asserts it can confidently state that no treatment with an ESD has ever resulted in a patient death or serious injury. The comment argues that FDA’s position on AEs is speculative and not backed by data and that underreporting would pertain to other alternative treatments for SIB or AB.

(Response) FDA disagrees. As discussed in the proposed rule, FDA believes that the scientific literature suffers from various limitations and has likely underreported AEs associated with ESDs for a number of reasons (see 81 FR 24386 at 24935). Perhaps most importantly, the devices have been studied only on a very small number of subjects, many of whom would have difficulty communicating or otherwise demonstrating AEs, including injuries. Although FDA did not identify death as a risk of ESD use, we have reason to doubt the commenter’s confidence about the lack of serious injuries related to ESD use.

For example, JRC provided no data regarding AEs in the resident summaries it submitted, and the submission includes no information to assess whether AEs were systematically planned for, tracked, or documented in any of the clinical data. A qualified clinician should have inquired about AEs with open-ended questioning at predefined times after each use of the GED; there is no indication this occurred. Therefore, these data are inconclusive regarding whether AEs occurred. As we stated in the proposed

rule, 66 patient case histories spanning a 23-year period did not report any AEs, which is highly unusual over such a long time. For instance, FDA expected to read about a known case of skin damage in these histories; however, there is no mention of that event. This may be because none of these case histories included systematically defined methods for short- or long-term AE monitoring.

In the Massachusetts hearing, JRC submitted only one paper about adverse effects of ESD use (Ref. 7). The paper acknowledges that few studies have systematically investigated adverse effects, and it does not include a statistical analysis because it did not collect enough data. Dr. McCracken testified that in the literature about the use of ESDs, “there has been almost no attempt to identify or examine side effects” (Ref. 14, day 9 at 604). He then stated that “concerns me. In every other field of investigation of medical treatment, this would be considered—we go to great pains to capture all of those types of side effects” (id., referring to “reactions such as fear, panic, vigilance, regression, attempts to avoid the shock. Basically heightened anxiety, traumatic-like symptoms.”). These support FDA’s position.

There may also be an underreporting bias due to impairments with provider recognition, which is related to the difficulties individuals would have communicating or otherwise demonstrating to providers AEs including injuries (see 81 FR 24386 at 24398). SIB and AB are exhibited at disproportionately high rates by people with intellectual or developmental disabilities. Notably, many such people have difficulty communicating because of such disabilities. This difficulty is part of what makes these individuals members of a vulnerable population. Although some individuals were able to offer their opinions to FDA at the Panel Meeting, through interviews, and in the docket, most individuals at JRC currently subject to ESDs who have reported IQ scores, have scores that indicate their intellectual impairments are profound, severe, or moderate. This indicates that those individuals at JRC are, to varying degrees, vulnerable due to difficulty communicating. Thus, FDA cannot conclude that communicative individuals are representative (with respect to their communicative abilities) of other individuals subject to ESDs.

The bulk of the articles describe case reports or series, employing only retrospective reviews of clinical experience, not prospective studies. Because such retrospective reviews do not systematically plan for the

identification of AEs in advance, their assessment of such has limited value. In contrast, prospective studies that include plans to observe and record AEs from the outset generally provide greater confidence in their assessment of AEs. Further, most of the research articles were published in the 1960s and 1970s, before significant advances in the ability to diagnose and classify psychological AEs such as PTSD. Most of this dated research did not adhere to modern standards for AE monitoring.

Although a ban does not require proof of harm, evidence of actual harm helps inform the analysis, so FDA extensively reviewed the available data and information for AEs associated with the use of ESDs. FDA relied on that data and information to understand specific risks and dangers that ESDs present to individuals’ health (see 81 FR 24386 at 24393). FDA considered data and information from one prospective case-control study and one retrospective chart review of 60 subjects that reported AEs. Note that the case-control study did not systematically assess AEs. These references reported:

- The emergence or intensification of self-restraint;
- low-intensity SIB that eventually resulted in tissue damage;
- temporary skin discoloration that cleared up in a few minutes or days; and
- “collateral behavior” not reported as AEs, including emotional behaviors, tensing of the body, and attempts to grab or remove the device.

In addition, FDA considered 25 case reports or series encompassing 66 subjects that included an assessment of AE occurrences. These references reported:

- Symptom substitution, including head-snapping, and possible symptom substitution, including increased incontinence;
- escape behavior;
- possible hostility and retaliation;
- anticipatory fear and avoidance upon observing the experimenter’s initial movements to deliver a shock, immediately developing fear of the device itself, and fear (phobic response) of buzzing sounds;
- aggression, including accounts of surrogate retaliation, self-aggression, lesser aggressive action, aggression fantasies, threats and warnings;
- development of episodic bursts of SIB and aggression toward others;
- crying, increases in crying, cries of pain, whimpering;
- shivering;
- statements that the shocks were painful and grimacing;
- panic;

- extreme anxiety (consisting of screaming, crying, attack, and escape attempts);
- freezing (generalized behavior suppression) including an observation of pseudocatatonic sitdown;
- initial increase in self-mutilative behavior and emotionality;
- decrease in happiness or contentment and increased dependency;
- slight local tremor in the thigh due to the shock;
- arc burns to the skin;
- lesion or bruise on the skin that resolved in 1 week and slightly reddened areas;
- flinching;
- perspiration; and
- demonstrating other undesirable behaviors, including smearing feces, spitting, stamping feet, swearing and using racial epithets, making obscene gestures, rolling eyes, and imitating others.

A later submission of 68 case reports revealed three subjects for whom AEs were noted; however, FDA is aware of at least one AE (skin burning) that did not appear in that set of reports (Ref. 5 at 69; Ref. 15 at 135–36). These documents reported:

- Urinary retention;
- arm pain;
- seizure;
- injured foot;
- angioma (an abnormal growth) below the ribs that did not need treatment;
- lipoma on arm; and
- cloudy urine specimen.

These AEs occurred while the residents were subject to an ESD, but the reports do not describe an evaluation of whether the ESDs caused or related to the AEs. Note that FDA is not identifying all of these as risks of ESDs for SIB or AB.

Ten other case reports or series did not assess AEs, and 6 articles, encompassing 11 subjects in total, noted that the researchers did not observe AEs in their subject population.

Because of the likely underreporting of AEs in the literature, FDA carefully considered the risks identified through other sources, which provide further support for the risks reported in the literature. These sources beyond the scientific literature indicate that ESDs are associated with additional risks such as suicidality, chronic stress, neuropathy, and injuries from falling (see 81 FR 24386 at 24399). Although JRC has only publicly acknowledged the risks of pain and erythema, its own documents provide evidence that aversive interventions such as ESDs are associated with several other risks,

including nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and withdrawal from usual activity (see 81 FR 24386 at 24398).

With regard to underreporting AEs pertaining to other treatments, the comment specifically refers only to pharmacotherapy. However, the studies conducted for approval of the drugs provide a better baseline to understand their risks than that available for ESDs, and the studies supplement our understanding from spontaneous postmarket reports of AEs. As a result, the possibility that the pharmacotherapy poses risks additional to those that have been reported is much less of a concern in FDA's consideration of state-of-the-art treatment for SIB or AB than is the likelihood of underreporting of AEs associated with ESDs in FDA's consideration of ESD risks. For example, to obtain drug approval for the pharmacotherapies used in relation to SIB and AB or the underlying conditions, the sponsors conducted Phase I clinical trials that included neurotypical individuals to assess the safety profiles of the drugs, meaning the subjects of the study were generally better able to communicate AEs than the individuals on whom ESDs for SIB or AB have been used. Further, such trials assessed AEs according to prospectively determined protocols. In the Phase II and Phase III trials, AEs were also systematically monitored in the intended-use population. Thus, in the case of pharmacotherapy used for SIB or AB, the safety of the drugs has been studied in formal trials that provide a much better understanding of their risks than the much more limited data that exist for ESDs.

In contrast, the safety of ESDs has not been equivalently studied. This is not to suggest that a finding of substantial equivalence to an existing device type must rely on adequate and well-controlled studies as if the sponsor sought new drug approval. Rather, it indicates to FDA that the safety profile for pharmacotherapy used in relation to SIB and AB or the underlying conditions is better understood than the safety profile of ESDs for SIB or AB, in particular that AEs are better understood. The data and analysis for such pharmacotherapies are more robust because the available data and information for ESDs suffer from various limitations discussed throughout this rulemaking, whereas the clinical studies for these drugs do not. As such, the pharmacotherapy premarket data provide a more complete understanding

of risks, reducing any concern regarding underreporting of AEs.

The commenter agrees that other state-of-the-art approaches such as positive behavioral treatments pose little to no risk. As discussed in the comment responses regarding the state of the art, the only risk that FDA found to be associated with positive behavioral treatments is the potential risk of "extinction bursts," an upsurge of the actual undesirable behavior, which is easily recognized and quickly mitigated by competent therapists.

(Comment 27) Quoting from Ref. 42 and Ref. 16, a comment states that "most published accounts report few, if any, side effects from treatment" and that "overall, there was little to suggest the development of adverse side-effects." The comment argues that positive side effects are most often observed, including relief from other symptoms. The comment also argues that scientific research "does not have a shelf life."

(Response) FDA disagrees with the characterization of the published accounts as well as the implication that previous scientific research cannot be understood in a different way over time. FDA considered the cited references in their entirety at the proposed rule stage, including in the context of ethics and treatment options prevailing at the time the research was conducted. We note that this comment relies on research from earlier decades; both references date back to 1975, well before the development of less-invasive behavioral treatments. After considering these references in light of then-prevailing ethics and conceptions of harm, FDA is not persuaded that these references speak to modern standards of care regarding "positive side effects."

As to "adverse side effects," we believe that these and other early studies underreported AEs for various reasons discussed in the proposed rule and other comment responses, were subject to lower peer-review standards for observation and reporting relative to modern standards, and did not have the benefit of recent decades of research into the treatment of SIB and AB. As a result, the articles quoted by the commenter have various weaknesses that undermine the commenter's position.

First, Ref. 42 notes that in its literature review "only two articles [Refs. 40 and 43] consider in any detail the problems associated with aversion in self-injurious behavior or in the severely retarded." Further, "even those accounts which have been included vary considerably in the adequacy of the information given; particular

deficiencies being the lack of adequate clinical data about the subject or the results of previous treatment and the short duration and variability in methods of recording of baseline observations, bearing in mind that self-injurious behavior tends to fluctuate in intensity over time" (Ref. 42). The article also notes the importance of the concomitant positive behavioral program in producing positive side effects. Finally, the article concludes: "an answer to the problems associated with aversion will not reach any rapid solution and it is therefore essential that treated cases are properly documented and reported" (Ref. 42). Thus, the commenter's reliance on this article as support for its position that ESDs cause "few, if any, side effects" is not persuasive.

Similarly, the authors of Ref. 16 conclude that "the work with this technique is still at a preliminary stage and the apparatus is not yet sufficiently trouble-free to warrant its use outside research settings." Thus, the commenter's reliance on this article as support for the statement that there is "little to suggest the development of adverse side-effects" is also unpersuasive.

Other literature submitted by the commenter supports FDA's findings of risks. For example, Ref. 39 reports risks from other studies of elicited and operant aggression, other emotional responses (e.g., crying), decreases in appropriate behavior ("generalized response suppression"), escape from or avoidance of the punishing agent or situation, and caregivers' misuse of punishment (see also Ref. 44). Further, according to Ref. 39, aggression and emotional responses may be more likely to occur when the individual is exposed to unavoidable and intense aversive stimulation. Ref. 36 reports the risk of untargeted positive behavior being modified by the device. Ref. 40 includes negative reaction to authority figures, the increase in behaviors undergoing treatment, prolonged treatment potential, production of undesirable emotional states, behavioral rigidity, general disruption of cognitive processes, production of neurotic syndrome, suppression effects not specific to responses punished, and chronic emotional maladjustment. (See also Response 19 discussing pseudocatatonic states and generalized behavior suppression.) Ref. 45 discusses the risks of an unreliable apparatus, including inappropriate intensity of shock, inconsistent delivery of shock, inappropriate delay of shock, or inappropriately prolonged shocks. Ref. 46 enumerates 19 negative side effects.

Another article submitted by the commenter acknowledged that few studies have systematically investigated side effects of skin shock (Ref. 47). The few studies reporting the potential benefits of the devices that were published in more recent years similarly did not systematically report AEs or include safety outcome measures (see Ref. 47).

Recent testimony from the Massachusetts hearing corroborates that AEs are understudied (Ref. 14, day 9 at 604 (McCracken)) and that certain risks are underreported and undertreated in people with developmental and intellectual disabilities (Ref. 14, day 26 at 1519–20 (Miner)). Other testimony indicates that shocks are rarely used because of negative side effects, for example, avoidance, emotional responses, and perpetuation effects (see Ref. 14, exhibit 494 (Spiegler 2014)). Similarly, JRC's own documents state that side effects (i.e., risks) can include emotional reactions, aggressiveness, escape from or avoidance of the punishment situation, increased unwanted behaviors, and self-perpetuation of punishment (Ref. 38), as well as exacerbation of violent behaviors (Ref. 48).

Keeping the foregoing in mind, the quotations of Refs. 42 and 16 indicating that published accounts report few, if any, negative side effects do not fairly characterize the decades of research since 1975. In the intervening decades, clinicians have expanded what they consider to be negative side effects and have made significant advances in the ability to diagnose and classify negative psychological effects. For example, pain is itself a harm, yet earlier studies did not view the pain as a harm.

As we have explained, providers' and researchers' concerns about intentionally inflicting such conditions upon a vulnerable patient population led to advancements in behavioral therapy (see 81 FR 24386 at 24404). In fact, Ref. 42 advocated for active research to establish "alternative forms of treatment" because he recognized the ethical concerns presented by this treatment, particularly in a patient population that cannot give consent (Ref. 42). In the case of using ESDs for SIB or AB, the ethics of using restrictive interventions on such a population contributed to the evolution of treatments and of understanding their attendant risks.

While empirical findings may not have a "shelf life," the understanding of the completeness and implications of those findings may change as science evolves, which it has with respect to assessment of risks for ESDs. Based on

such evolution, for example, because the decades-old references did not consider pain, anxiety, or other such sequelae as harms—nor did researchers systematically monitor for AEs according to current standards—FDA continues to regard such references as poor indicators for the occurrence of AEs.

(Comment 28) A comment disputes FDA's position regarding AE underreporting due to communication difficulties on the part of intellectually and developmentally disabled individuals by arguing that individuals subject to ESDs "many times" demonstrate improved communication, and that communication can be through nonverbal means, assisted by augmentative communication devices such as a picture board.

(Response) Although FDA acknowledges that some of these individuals may demonstrate improved communication and that communication can be through nonverbal means, this does not change FDA's view that many individuals manifesting SIB or AB would have difficulty communicating AEs and injuries, verbally or otherwise, and that this likely results in underreporting of AEs. Behavioral interventions typically include elements intended to improve communication skills; this does not mean that all or most individuals will be able to adequately communicate AEs.

We also note that, although augmentative communication devices may assist staff in communicating with nonverbal individuals, this is nevertheless evidence that those individuals have difficulty communicating. The comment does not explain or give examples of how these devices compensate for difficulties communicating AEs and injuries, nor does the comment present evidence contradicting the likelihood of atypical pain expression. FDA maintains that many individuals who present with SIB or AB would have difficulty communicating or otherwise demonstrating AEs and injuries and the Panel agreed (see Ref. 15 at 54, 155, 355).

(Comment 29) One comment questions FDA's claim of researcher bias, and it notes that in some "N-equals-1" studies, the researcher is blinded, which eliminates the researcher's bias.

(Response) FDA discussed numerous reasons in the proposed rule that researcher bias and author conflicts of interest may have influenced study results and conclusions, for example with respect to underreporting of adverse events, 81 FR 24386 at 24395,

and regarding poor study design, 81 FR 24386 at 24400 to 24401, and this comment does not address any of them. Instead, it points to the testimony of one of its experts regarding some blinded N-equals-1 studies, a study design that combines information from single-subject trials. We note that no N-equals-1 studies have been conducted on the use of ESDs for SIB or AB. Thus, although some study designs may reduce or eliminate researcher bias, this observation does not reflect the state of research into ESDs used for SIB or AB, and FDA is not revising our views regarding bias or the reduced weight we have given biased evidence.

(Comment 30) A comment asserts that JRC uses extensive measures to ensure ESDs are applied only to refractory patients, for example, evaluating each patient with a functional behavioral assessment (FBA) performed by a JRC clinician; first attempting PBS approaches; exhausting all other options; and obtaining a prior court order with the involvement of multiple parties. In the commenter's view, FDA fails to discuss and consider these measures in the assessment of risks.

(Response) FDA disagrees with the comment's rationale on several points. First, FDA did consider these measures. However, as we explained in the proposed rule, no clinical criteria identify refractory patients, and no rigorous or systematically collected data distinguish a refractory subpopulation that does not respond to other available treatments (81 FR 24386 at 24406). Similarly, members of the Panel unanimously concluded that such a subpopulation seems to exist but is very difficult to define (81 FR 24386 at 24406). Thus, as we explained, although evidence indicates that a very small subpopulation of refractory individuals may exist, that subpopulation is difficult if not impossible to define (81 FR 24386 at 24412). We are not persuaded that JRC has successfully defined a refractory subpopulation by exhausting a selected list of options, and this undercuts the certainty in JRC's claim that its patients are uniquely refractory.

Regarding exhaustion of options, we also explained that the available evidence casts doubt on whether JRC in fact applies the devices as a last resort after adequately attempting all other measures, and the evidence shows that some patients JRC had considered to be refractory were transitioned successfully to other treatments (81 FR 24386 at 24412). As we describe in more detail in Responses 39 and 44 to 46, additional data and information cast further doubt on the adequacy of JRC's attempts at

alternative treatments. In other words, this undermines claims that ESD use can be limited to a truly refractory subpopulation.

More importantly, these measures to limit use of the device to a specific subpopulation in no way reduce or eliminate the risks posed by ESDs, and the commenter does not argue they do. Even if the measures were effective, they would merely limit the number of vulnerable individuals exposed to the risks; those individuals would still be exposed to the same risks as they would be in the absence of such measures. Rather than showing risk mitigation, the commenter's statements about limiting the exposed population provide support for the severity of the risks: If as the commenter claims, the devices are low risk, such measures would not be needed. Thus, the use of such measures fails to reduce the risks even as the reliance on such measures tends to confirm the severity of the risks.

Even if the risks could be limited to a very small subpopulation, this would not alter FDA's determinations that the risks are substantial and unreasonable. This is because, as discussed in the comments regarding effects, effectiveness has not been established in any population of patients exhibiting SIB or AB. Further, as discussed in the comments regarding the state of the art, positive behavioral approaches, sometimes alongside pharmacotherapy, have generally been successful even in the most difficult cases. However small this patient population may be, these vulnerable individuals, like all individuals, are entitled to the public health protections provided in the FD&C Act.

D. Effects of ESDs on SIB and AB

(Comment 31) A comment states that FDA acknowledges ESDs have been shown to reduce SIB and AB.

(Response) In the proposed rule, FDA acknowledged that ESDs may cause the immediate interruption of SIB or AB (81 FR 24386 at 24387) if the shock is applied while the SIB or AB is occurring. We also explained that some evidence suggests ESDs reduce SIB and AB in some individuals, but this evidence cannot be generalized because the studies suffer from serious limitations such as weak design, small size, confounding factors, outdated standards for study conduct, and study-specific methodological limitations (81 FR 24386 at 24400). We are also concerned about potential bias in some of the evidence of effectiveness related to lack of peer review and conflicts of interest (81 FR 24386 at 24401). Other evidence shows that ESDs are

completely ineffective for certain individuals. For these reasons, FDA concluded that the evidence is sufficient to show that ESDs may interrupt behaviors when a shock is applied, but the evidence is otherwise inconclusive and does not establish that ESDs improve the underlying condition or condition individuals to achieve durable reduction of SIB or AB for a clinically meaningful period of time (81 FR 24386 at 24399 to 24403).

(Comment 32) One comment interprets FDA's statement in the proposed rule that, "the possibility that some patients are refractory [to other treatments] does not necessarily mean that ESDs would be an effective treatment" to mean that FDA believes ESDs should be banned because they are not effective for every individual with SIB or AB.

(Response) FDA disagrees. The statement referred to in the comment only makes the point that the fact that one treatment does not work for a patient or group of patients does not mean that a different treatment will work. FDA understands that devices are not always effective for every individual with the condition the device is intended to treat; this is not a reason that FDA is banning ESDs.

(Comment 33) A comment argues that, although there are no randomized controlled clinical studies of ESDs for SIB or AB, the available data, including over 100 published peer-reviewed articles, among other sources, amply provide evidence of the safety and efficacy of ESDs for SIB or AB. The comment provides a table summarizing 162 references discussing the use of skin shock.

(Response) FDA disagrees. As the comment acknowledges, these data have been provided to FDA and reviewed by the Agency, and FDA has also reviewed all of the additional information provided by commenters. We weighed the evidence according to factors that we explained in the proposed rule (see 81 FR 24386 at 24393). Where FDA has reconsidered the interpretation or significance of specific sources or claims in response to comments on the proposed rule, we have explained the reevaluation and how it affects the analysis in the appropriate section of this final rule. For example, based on additional data and information, we believe the proposed rule understated the harm of pain (see Response 13), and we no longer consider affection-seeking a risk of ESDs (see Response 16(c)). In other cases, we have elaborated on the significance of certain statements identified in the available information,

for example with respect to the potential risk of seizures (see Response 24).

FDA's review of the references cited by the commenter, along with the corresponding comments, does not change our conclusion that, beyond the ability of ESDs to cause immediate interruption of the behavior at the time of shock, the evidence is otherwise inconclusive with regard to the benefits and effectiveness of ESDs for SIB or AB. We continue to conclude that the evidence does not establish that ESDs improve the underlying disorder of which SIB or AB is a symptom, or successfully achieve a durable reduction of SIB or AB for clinically meaningful periods of time by conditioning individuals' behavior.

FDA previously reviewed 44 of the 162 references highlighted by the comment, which we discussed in the Executive Summary for the Panel Meeting and the proposed rule (see 81 FR 24386 at 24393). There were few comments regarding ESD effectiveness with respect to the references previously discussed by FDA, and FDA continues to view these as we did at the proposed rule stage. Note that one reference appeared twice, meaning the total of summarized references is 161. The references that FDA had not previously reviewed are:

- 19 case reports, 10 of which (involving 17 total subjects) provide some information regarding durability of effects;
 - 10 literature reviews, all of which summarize literature that FDA has already reviewed;
 - 41 references with limited or no discussion of ESDs, including opinion pieces and miscellaneous documents that do not directly bear on ESD risks or effects—these have limited relevance to this rulemaking;
 - 38 reports on treating conditions other than SIB or AB—these also have limited relevance to this rulemaking; and
 - 9 unpublished presentations or other documents that the commenter did not provide and FDA could not locate, including two written by JRC's former director-founder that are no longer available on JRC's website.
- We focused our review of these references on the 64 references (45 discussed in the proposed rule and 19 cited in comments) that discuss patient data from clinical studies on ESDs for SIB or AB. With the exception of the one case-control study discussed in the proposed rule (see 81 FR 24386 at 24393, discussing Ref. 17), all of the other studies are case reports or literature reviews pulling from these case reports.

The case reports show immediate interruption of target behaviors at the time of shock application. One study on subjects with Lesch-Nyhan syndrome exhibiting SIB and AB shows no effectiveness whatsoever (Ref. 49), and a few report ultimate failure after a period of apparent success. However, all of the other case reports appear to demonstrate immediate interruption of the behavior at the time of shock application. FDA continues to conclude that the evidence shows that ESD shocks generally cause immediate interruption of the behavior that is occurring when the shock is delivered, provided the individual has not adapted to the shock, which has been shown to occur for some individuals.

More critical to the evaluation of the effectiveness of ESDs for SIB or AB is their ability to achieve durable effects by aversively conditioning behavior. A durable effect is one where an individual develops a conditioned response, so the target behavior, along with the frequency of shocks, is significantly reduced over a clinically meaningful period of time, either while the individual continues to wear the ESD or after the ESD is removed. Half of the references, 32 of 64, include at least some information regarding durability of ESD effects.⁷ Several of these references report cases where there was some short period of reduction in target behaviors followed by failure. Most report a reduction in the target behavior ranging from a few months up to several years, particularly with continued (less frequent) ESD use. However, conditioned reduction of SIB or AB over clinically meaningful periods of time is much more difficult to demonstrate than immediate interruption of behaviors because, for example, data regarding such are more vulnerable to the errors that well-designed and controlled studies are intended to minimize. Establishing durable conditioning demands well-conducted clinical studies and data spanning longer periods. For example, an individual may undergo several different behavior modification techniques over a period of time, and it is more difficult to draw conclusions regarding the effectiveness of ESDs from a study that does not control for such confounding factors than from a study that did control for them. As a result of such weaknesses and limitations, as described in the paragraphs that follow, the limited data that currently exist for

ESDs for SIB or AB are inadequate to establish durable conditioning.

As the comment recognizes, there are no randomized controlled clinical studies of ESDs for SIB or AB; there are only case reports and, as discussed in the proposed rule, one prospective case-control study on 16 subjects, 8 in the device group and 8 in the control group (see Ref. 17). The comment acknowledges this study has an extremely small sample size. The results of the case-control study are further limited because the study was not randomized or blinded, and it used an unvalidated surrogate endpoint (decrease in mechanical restraint). Case reports are, by definition, extremely small in size; the ones regarding ESDs for SIB or AB typically include fewer than five subjects, and often only a single subject. They have no control group, blinding, or randomization, do not test statistical significance, and the results are unlikely to be generalizable across subjects.

The particular case reports cited in the comment suffer from various other shortcomings that limit the ability to draw conclusions from their results regarding the effectiveness of ESDs for SIB or AB. Perhaps most importantly, many subjects were given concomitant treatments such as positive reinforcement or time-outs; therefore, it is unclear how much, if anything, the use of ESDs contributed to the observed reductions in SIB or AB. Many other case studies lacked sufficient detail to determine whether concomitant treatments were given. Other information important to assessing ESD effectiveness was often missing, such as details regarding the subjects and their particular forms of SIB or AB, baseline behavior measurements, device output and electrode locations, and shock administration protocols.

Further, most of the studies were conducted several decades ago and do not conform to current study conduct, reporting, or peer-review publication standards. Results were sometimes reported anecdotally and were not always recorded by a trained investigator, which raises questions regarding their reliability. Most studies lacked predefined, clinically meaningful endpoints, and typically study sessions and followup were of inadequate duration to assess effectiveness for a clinically meaningful time period or generalizability to the subjects' everyday environment. As a result of these limitations, the data are inadequate to draw any scientific conclusions regarding the durability of ESD effects on SIB and AB.

⁷ We had not previously discussed 10 of these references in the proposed rule or Panel Executive Summary, Refs. 50–59.

(Comment 34) A comment notes that a literature review discussed in the proposed rule states, “basic findings suggest that relatively intense punishers may be associated with successful long-term outcomes” (Ref. 60). The comment asserts this demonstrates that aversives are effective and durable.

(Response) FDA disagrees. As discussed in the proposed rule, even though the cited article opines that research findings suggest sufficiently intense punishers such as ESDs *may* be associated with long-term success, it cautions that such findings suffer from various limitations, and the authors conclude that “[u]ntil additional research on long-term maintenance is conducted, practitioners and caregivers should not assume punishment will remain effective over the long run.” (81 FR 24386 at 24399, citing Ref. 60). The article explains that most of the time periods evaluated in the literature on punishment are brief, which may limit their applicability to treatment outcomes in clinical settings, and these studies have shown inconsistent outcomes in maintaining a reduction in target behavior (see, e.g., Refs. 19, 20, 61 to 64). According to this article, conclusions about applied findings on maintenance of effect are difficult to draw for a number of reasons, including that relapse cases are less likely to be submitted or accepted for publication than successful ones. Thus, the reference does not demonstrate that aversives such as ESDs achieve durable reduction of SIB or AB for a clinically meaningful period of time. Rather, the article questions their effectiveness, and ultimately concludes that current knowledge is insufficient to support clinical application.

(Comment 35) A comment states that FDA badly mischaracterized a reference, Ref. 65, in the proposed rule, and that the findings in the reference contradict claims that ESDs cannot be successful unless continuously applied.

(Response) FDA disagrees. Providing only an excerpt from the article’s abstract in support of its assertion, the comment misrepresents the findings of this article, which does not purport to study the effects of punishers, much less reach any conclusions regarding ESD effectiveness. Rather, the authors studied the ability to terminate the use of punishment-based procedures—described as “multiple, ‘aversive’ treatments” that “were discontinued abruptly”—in favor of less invasive alternatives, specifically multielement positive interventions. The article explained, “The question posed was how do adults with developmental disabilities and seriously challenging

behaviors respond in the long-term when they are no longer exposed to negative and highly invasive procedures?”

Interventions that included contingent electric shock from ESDs were used for each subject prior to the positive interventions studied by the authors. The article acknowledges, “[i]t is possible, of course that the prior invasive [restrictive] treatment contributed to the long-term outcomes presented in this report,” but concludes that its “results are encouraging in demonstrating that punishment-based approaches can be terminated, alternative strategies can be substituted, and through a clinically responsive system of monitoring and decision-making, behavioral adjustment can be supported without having to resort to invasive forms of treatment” (Ref. 65). In sum, the authors were not validating the initial use of punishers or evaluating their long-term effectiveness but rather studying the ability of multielement positive interventions (*i.e.*, state-of-the-art approaches) to supplant punishment procedures, finding encouraging results that behavioral adjustment can be supported without invasive forms of treatment.

(Comment 36) One comment states that a reference cited in the proposed rule, Ref. 66, included “surprising findings” on the use of shock “pertaining to ‘the immediate increase in socially directed behavior, such as eye-to-eye contact and physical contact, as well as the simultaneous decrease in a large variety of inappropriate behaviors, such as whining, fussing, and facial grimacing . . .’” The comment asserts that FDA selectively used information from this article for our own purposes.

(Response) FDA disagrees. FDA referred to this article in the proposed rule for several reasons, including: To support some of the risks posed by ESDs; to support the occurrence of adaptation, wherein a patient grows accustomed to a particular level of shock and no longer responds; and to support the ability of ESDs to immediately interrupt behavior occurring at the time of shock. The cited article studied short-term treatment and reported some immediate benefits from the use of ESDs for SIB or AB, as stated in the proposed rule. However, regarding longer-term followup, it states: “Although the immediate ‘side-effects’ of punishment point in a desirable direction, one should be less optimistic about long-term behavioral change under certain conditions. We can supply few data which exceed a couple of months’ followup, and in the

case of only two children have we had the opportunity to conduct follow-ups for as much as 1 year, while the suppression of self-destruction was being maintained.” This is consistent with FDA’s determination that the data suggesting durable effectiveness of ESDs are generally weak, and the reference’s statement is also consistent with the commenter’s criticism (elsewhere in its comments) of this reference’s “extremely small sample size” of three subjects.

It is also important to note that this article was published in 1969, so as explained elsewhere, we believe that it suffers from outdated methodology, such as a lack of systematic observation and reporting of AEs. Thus, the article’s characterization of “side effects” as pointing in a “desirable direction” must be considered in this light. FDA considered the entire reference with regard to both benefits and risks and continues to regard the reference as we did for the proposed rule.

(Comment 37) A comment asserts that FDA’s claims that Dr. Israel’s 2008 and 2010 papers (Refs. 47 and 67) were not peer reviewed, and that they failed to disclose Dr. Israel’s affiliation with JRC, are incorrect. The comment states that the copy of the 2008 review posted by FDA includes an apparent printing error that omitted the references to Dr. Israel’s disclosure.

(Response) FDA acknowledges the apparent printing error in the omission of Dr. Israel’s disclosure in the 2008 paper. Thus, other readers may have been adequately notified of any potential bias. However, as we explained in the proposed rule, FDA was aware of the affiliation and took into account the possible conflicts of interest, which stem from the facts that Dr. Israel was the founder of JRC and, at the time his papers were published, was on the journal’s editorial board and thus part of the reviewing and approving body (for his own papers). As such, this printing error does not affect our conclusion with respect to Dr. Israel’s potential bias. As we stated in the proposed rule, possible conflicts of interest do not, on their own, invalidate results. However, we continue to view Dr. Israel as a potentially biased source and weigh this evidence accordingly.

With regard to peer review, the commenter simply asserts without explanation that the papers were peer reviewed. However, as we explained in the proposed rule, we determined that the publications (both 2008 and 2010) were not peer reviewed because the articles were only reviewed by the journal’s editorial board rather than an independent expert whose sole role was

to verify accuracy and validity (see 81 FR 24386 at 24401).

(Comment 38) One comment asserts that all of JRC's residents' harmful and dangerous behaviors decreased substantially as a result of treatment with the GED device, as evidenced in JRC's resident case reports, behavior tracking charts, and analyses from the past 16 years. The comment asserts this data set is extraordinarily robust because the individuals reside at JRC and are continuously monitored. The comment also asserts this data and information demonstrate the effectiveness of ESDs for SIB or AB for refractory patients.

(Response) FDA disagrees that this is a robust data set, and this information does not change FDA's assessment of the effects of ESDs for SIB or AB. The case reports and other information submitted by JRC about its residents on whom ESDs have been used appear to indicate that their SIB and AB decreased substantially once they began wearing the GED and remained at low levels for years. However, as explained in the paragraphs that follow, this information suffers from several serious methodological limitations that prevent FDA from drawing any scientific conclusions regarding ESD effectiveness based on it. For example, these are resident records, not study data, and they also suffer from the same limitations that generally apply to the case studies discussed in the literature. In addition, the manner in which the information was collected and documented undermines its reliability.

In particular, these resident records are anecdotal and do not amount to *study* data. The information was collected by JRC, which did not take measures to minimize the impact of subjectivity and potential bias. Important measures that its employees did not take include having an investigational plan and study protocol, running an analysis to demonstrate scientific soundness, validating methodology and endpoints, and selecting qualified investigators. JRC also failed to implement features designed to minimize confounding factors and other types of bias, such as a control group, blinding, and randomization, the importance of which are discussed in the proposed rule and in the responses to other comments. These records also suffer from the limitations that apply to extremely small studies. Although in 2016 JRC submitted case summaries for 68 residents (and has applied the devices to close to 300 individuals over the years, including about 51 then subject to the devices), we consider these data to

be 68 individual resident summaries, not a single study including all residents, because the records do not show, for example, that conditions were controlled across individuals or subgroups of individuals.

Further, confounding factors and uncontrolled conditions make it very difficult to attribute JRC's observed improvements in behavior to the GED device or draw any conclusions about its effects. For example, according to these records, most of the individuals on GEDs received concurrent treatment with various forms of behavioral therapy, including positive behavioral programming and various differential reinforcement programs, counseling, and functional communication training. Without adequately controlling for, or adequately documenting the formulation, application, and effects of the other behavioral intervention components, it is difficult if not impossible to differentiate effects of the GED from effects of behavioral treatments. Additionally, these records indicate that JRC targeted different behaviors during different time periods. As a result, many of the tracking charts show highly variable behavior, in some instances showing some target behaviors decreasing for an individual while other target behaviors did not decrease for that individual, and thus shocks continue to be applied. This makes it difficult to assess overall ESD effectiveness.

Where data represent a relatively small number of individuals, detailed, systematic observations are critical to reducing uncertainty regarding results. Yet the information submitted by JRC fails to include important details regarding how the data were collected and recorded. This creates considerable uncertainty as to its significance and reliability and prevents us from drawing clinically meaningful conclusions regarding the benefits of the GED from the limited data provided in the case summaries. For example, the information lacks key details regarding the time at which the device was applied, the specific behaviors targeted, behaviors that occurred prior to administration of shocks, criteria for counting behaviors, the number of electrodes and their location on the body, which ESD model was used, frequency and duration of data collection, who determined a behavior to be SIB or AB, who recorded the count data, and the medical training (if any) or qualifications of those recording data to evaluate the residents. The information submitted to FDA suggests that JRC often applied multiple devices at once to single individuals, but the

submissions do not explain why this was necessary or how the number of devices was determined; the submissions only provide gross detail, for example, that shocks were indicated for "health-dangerous behavior." Finally, the charts include little information regarding the individuals and their behaviors before and after ESD use, making it difficult to draw conclusions regarding how the devices affected the target behaviors.

(Comment 39) A comment argues that the ESD shock is applied to help residents identify their dangerous behaviors for purposes of reducing the frequency of that behavior. As residents learn to identify and control their dangerous behaviors, the number of shocks delivered decreases. The comment asserts that, for a significant portion of JRC residents, the duration of effects from ESDs for SIB or AB is lasting as demonstrated by the numerous residents who have been transitioned or "faded" off of the GED and no longer manifest SIB or AB.

(Response) Although ESDs may interrupt behaviors occurring at the time of shock, FDA has not seen adequate evidence demonstrating that ESD shocks produce a conditioned response. Additionally, although the ability of ESDs to condition individuals not to engage in SIB or AB after removing the device is part of the evaluation of ESD effectiveness, fading itself is not demonstrative of effectiveness. Fading of the GED is an indication of JRC's decision to reduce or cease use of the device for an individual, and submissions from JRC do not establish that it makes such decisions consistently, much less that it adequately establishes that the device caused changes in behavior. Further, SIB and AB can exceed pre-baseline levels once an ESD is removed, as has been observed in the literature. This is partly why, as discussed in the previous comment response, FDA disagrees that the resident data submitted by JRC demonstrate a durable effect for ESDs for SIB or AB.

With respect to individuals transitioned off of the GED, only a small percentage of individuals at JRC have been completely faded off of the GED. According to the records submitted by JRC for the 68 residents on whom ESDs have been used, only 13 (19 percent) have been completely faded, and the duration of ESD use prior to fading ranges from 3.5 to 23 years. According to the summary information for the 189 residents on whom ESDs have been used since 2000, which is even less detailed than the 68 resident records, only 58 (31 percent) had been

completely faded off of the GED device at least 2 weeks before discharge from JRC.

Further, JRC provided no information regarding clinical protocols, treatment plans, or behavior frequencies for individuals after they left JRC. At the Massachusetts hearing, Dr. Blenkush stated that JRC has not systematically collected follow-up data on individuals after they leave JRC (Ref. 14, day 37 at 81). FDA is not suggesting JRC necessarily must collect followup data; however, such data are important to understanding the effects of ESDs. Based on the scant information provided, FDA is unable to determine, for example, whether behaviors worsened after leaving JRC or whether other non-aversive treatments are responsible for any successes. Overall, it is difficult if not impossible to evaluate the effects of ESDs, much less draw any conclusions regarding ESD effectiveness, from the fading data provided by JRC for the GED, without: (1) A standardized clinical assessment protocol (*e.g.*, specific behaviors targeted, criteria for counting behaviors, frequency and duration of data collection, who determined a behavior to be SIB or AB, who recorded the data, and the medical training or qualifications to evaluate patients of those recording data); (2) controlling for or adequately documenting the formulation, application, and effects of the other behavioral intervention components that were applied according to JRC's data; and (3) well-documented followup to determine whether behaviors worsened after ESD use discontinued at JRC or after leaving JRC.

The claim that these devices produce durable conditioning is further undermined by the fact that, as evidenced in the resident records submitted by JRC, the device has been used on many individuals for years and even decades. As Dr. Iwata explained during the Panel Meeting:

[M]y understanding of the way this whole process works is that within a given range in terms of interventions that we use, some are effective and some are not, and if they're not effective, you go on to something else. Now, electrical stimulation is designed to be very effective very quickly, which means that the individual should not experience very many stimulations, which means that very few people should habituate to the stimulus. And if they do, it's not really habituation; that is, they haven't adapted to it. It's simply ineffective, and you would move on rather than to step up the voltage, so to speak. To use an analogy, a small amount of lemon juice on the tongue might be another aversive event, but if that doesn't work, we don't put acid on the tongue.

(Ref. 15 at 142). Regardless of whether adaptation is the correct characterization, even JRC has acknowledged that its strongest ESD sometimes loses any effects it may have had in reducing target behaviors, necessitating the use of an alternative method to modify behaviors program instead of an ESD. Dr. Blenkush highlighted "a very comprehensive alternative behavior program" at JRC that was "very effective" after adaptation to the GED—4 even for patients engaging in SIB that could result in serious injury to themselves (Ref. 15 at 148).

(Comment 40) One comment states some Panel members recognized ESDs as potentially appropriate for certain patients and asserts that FDA has ignored the comments of several Panel members that there is evidence to demonstrate that ESDs for SIB or AB have beneficial effects, particularly in the refractory population treated at JRC.

(Response) FDA agrees that some Panel members opined that ESDs provide benefits for some patients but disagrees that we ignored these comments in the proposed rule and disagrees that Panel members opined that the benefits would be more likely to occur in JRC's patients. As explained in the proposed rule, approximately half of the Panel agreed that there was a benefit, but they qualified their answers by explaining that the evidence showed a benefit from the interruption and immediate cessation of the behavior and noted the weaknesses in the evidence (81 FR 24386 at 24401). Regarding refractory individuals residing at JRC, when asked specifically about the subpopulation for whom any benefits might manifest, most panelists stated that they could not define that subpopulation. Further, as noted in Responses 13, 32, and 43, being refractory to other treatments does not mean ESDs will be effective. However, overall, the Panel recommended to FDA that the Agency ban ESDs for SIB or AB, with the members taking into consideration potential benefits and risks of the devices, including use of the device in a refractory population. Accordingly, the Panel's overall evaluation of ESD effectiveness is consistent with FDA's.

(Comment 41) One comment says that expert testimony from the Massachusetts hearing supports JRC's argument that the GED is effective for the population on whom it is used at JRC.

(Response) FDA agrees that some of the expert witnesses at the Massachusetts hearing testified about the beneficial effects from the GED for

SIB or AB at JRC. For example, Dr. Susan Shnidman, a clinician, testified that she observed improvements in the behaviors of many JRC residents after beginning treatment with the GED, and Dr. Philip Levendusky, another clinician, acknowledged in his testimony that there are many examples where the GED had a positive impact on a JRC resident. Further, clinicians Dr. Mikkelsen stated, and Dr. Zarccone confirmed, that in many cases there was rapid deceleration in SIB after the use of the GED, with the problematic behaviors decreasing from hundreds per day to zero in a very short period of time.

While expert testimony regarding observed benefits of the GED in many individuals at JRC is certainly relevant to this rulemaking, and FDA has taken this information into account in our decision-making, much more important is the issue of durable, clinically meaningful, effectiveness of ESDs for SIB or AB. On this more scientifically complex issue, the expert testimony from the Massachusetts hearing generally cuts in the opposite direction and is consistent with FDA's assessment that the evidence is insufficient to establish behavioral conditioning or durable effectiveness.

For example, although Dr. Mikkelsen testified that the GED can suppress the behavior and that he has seen some residents' behaviors respond to the GED, he also testified that, based on JRC's spreadsheets regarding efficacy, the GED "doesn't have any statistically lasting effect" and that he does not believe the GED "actually changes the behavior in any lasting way" (Ref. 14, day 7 at 196). Dr. Geller testified, "[t]he 168 articles represent a small number of cases that have extremely mixed results. . . . The studies fail to show whether or not [contingent skin shock] is effective, if the outcome means that the individual could live a life without the self-injurious behaviors or would have aggression without shock" (see Ref. 14, day 21 at 49–60). Dr. McCracken testified regarding the design weaknesses and inadequate duration of observation of the majority of studies on ESDs for SIB, which are particularly detrimental due to the fact that SIB "waxes and wanes over time"; one "could mistakenly attribute those changes to the treatment if you don't have a comparison group" (Ref. 14, day 9 at 152). Dr. McCracken summarized that, "the use of painful electric shock lacks what any professional group would deem an adequate and well supported evidence base" (Ref. 14, day 9 at 85–86), and that he would never use

shock even if no other treatment worked (see also Ref. 14, day 9 at 149–50, 160).

Further, according to hearing testimony and an exhibit from Dr. Geller, for nearly half of the 87 JRC residents with GEDs between 2000 and 2014, the “peak 12-month period” during which they received the most GED shocks was after their first year using a GED at JRC. Based on Dr. Geller’s analysis of JRC data, the average time to peak applications was 2.7 years, and in some cases the peak was not reached until they had been receiving GED shocks for 8 years or longer. Dr. Blenkush of JRC criticized this analysis insofar as it did not include pre-2000 data; however, JRC did not provide this GED application frequency data to FDA. According to this hearing testimony and exhibit, JRC’s own data show that for many individuals, the frequency of GED shocks and hence, the frequency of SIB and AB, *increased* rather than decreased for some period of time after GED use began; for many individuals, the peak 12-month period was many months, and for some individuals, many years, after GED use began. This casts additional doubt on JRC’s assertions that the GED very quickly decreases SIB and AB and produces a lasting conditioning effect, as well as on the ability of ESDs to achieve durable conditioning generally.

E. State of the Art for the Treatment of SIB and AB

(Comment 42) A comment asserts that PBS is not a state-of-the-art treatment for individuals exhibiting SIB and AB, arguing that PBS is not formally defined by any authoritative professional body and that it has no professional credential or license. However, the comment also states that ESDs must be used in conjunction with positive approaches.

(Response) FDA disagrees that the lack of PBS-specific professional credentialing or licensing means it is not a state-of-the-art treatment for SIB or AB. As explained in the preamble to the proposed rule, and as FDA continues to maintain, state-of-the-art treatment for individuals exhibiting SIB and AB generally relies on multielement positive interventions such as PBS (81 FR 24386 at 24403–10; see also section I.A.). The comment cites the hearing testimony of Dr. Zarcone, a psychologist and board-certified behavior analyst, to show that there is no educational degree or licensing for PBS. However, elsewhere in her testimony, Dr. Zarcone states that the use of PBS is generally accepted practice for the treatment of individuals who have intellectual and developmental disabilities and severe

behavior problems (Ref. 14, day 13 at 98).

As we recognized in the proposed rule, multielement positive methods such as PBS or dialectical behavioral therapy (DBT) span several categories of intervention for a wide variety of purposes (Refs. 68 and 69). Likewise, the term “positive” can apply to many different treatment modalities (Refs. 9 and 70). This does not, however, mean that positive approaches are vague or ill-defined. To the contrary, a large body of scholarship as well as broad institutional support informs the use of multielement positive approaches like PBS.

To take PBS as an example, as we explained in the proposed rule, the Association for Positive Behavior Supports has adopted specific standards of practice for the elements that comprise PBS (Ref. 12). Multielement positive interventions that rely on FBAs, such as PBS, are described in academic journals, books, graduate training programs, and professional organization publications (Ref. 12). Likewise, other positive-only models such as DBT are well-defined and formally described (see Refs. 71 and 72). Although the comment here states that PBS is not formally defined, it elsewhere refers to techniques of PBS as a discrete subset of ABA techniques in which JRC employees have experience. Furthermore, the comment characterizes one provider, Dr. Zarcone, as a national expert on PBS, recognizing that PBS is a distinct, defined treatment approach for SIB and AB. We note that no professional organization publishes standards of practice for the use of ESDs, and no journals, graduate programs, or professional organizations focus on the skills necessary to use contingent electric shock (see Ref. 12).

Comments from healthcare providers who have experience treating patients with SIB and AB explain that state-of-the-art positive behavioral interventions are even more advanced and effective than the methods that FDA described in the proposed rule (e.g., PBS). FDA agrees. For example, in one form of functional behavior assessment referred to as “analog functional analysis,” clinicians identify the antecedents and consequences that maintain problem behaviors by experimentally replicating the events or conditions thought to trigger, incentivize, or reinforce the behavior, then develop a behavior plan based on modifying these antecedents and consequences (Ref. 73). According to Dr. Zarcone, analog functional analysis is the most rigorous and precise level of FBA, and it is now considered to be the “gold standard” in the field of

applied behavior analysis for individuals with severe problem behaviors (see Ref. 14, day 13 at 66–67, 71–72, 80). This is demonstrated by the exponential increase in the number of research studies relating to analog functional analysis in recent years: While there were only a handful of such studies before 1985, there were approximately 250 in the 1990s and almost 1,000 between 2001 and 2010 (Refs. 74 and 75).

The comment asserting that PBS is not a state-of-the-art treatment for SIB or AB concedes that state-of-the-art treatments available to patients with SIB and AB include, among other options, positive behavior therapy, and that, “PBS therapy is almost always the first line therapy in the treatment of numerous disorders, including AB and SIB, due to its limited risk profile.” The comment goes further, stating that ESDs “must always be used in conjunction with positive behavioral programming as part of a comprehensive care protocol individualized for the patient.” These statements contradict the comment’s assertion that approaches such as PBS are not within the state of the art.

In analyzing the state of the art in a device ban, the Agency assesses the risks of the device being banned relative to the risks of other treatments used in current medical practice for the same purposes. Positive behavioral treatment techniques have a very low risk profile, and FDA did not receive any comments suggesting otherwise. Even this comment concedes PBS is “low risk.” The only risk that FDA found to be associated with positive behavioral treatments is one posed by “extinction,” a common component of behavioral plans (see 81 FR 24386 at 24405). Extinction exhibits the potential risk of “extinction bursts,” an upsurge of the actual undesirable behavior, particularly manifested in the early stages of the intervention. If this upsurge in behavior poses a danger to the individual or others, then an extinction paradigm may not be a feasible option. The behavioral therapist would have to use a different treatment plan component to accomplish the same objective. However, extinction bursts would be easily recognized and quickly mitigated by competent therapists. With respect to SIB and AB, positive behavioral treatment alternatives present much lower risks than ESDs, supporting the conclusion that the risks posed by ESDs are unreasonable.

(Comment 43) Some comments argue ESDs are necessary options because positive-only behavioral approaches such as PBS are ineffective for certain patients, citing literature indicating that

PBS is not always effective for every patient in every situation, and pointing out that the Panel agreed that treatment options other than ESDs would not be adequate for all patients. One comment asserts that FDA has erroneously clung to the notion that the effectiveness of PBS to treat SIB and AB is an absolute and that FDA was not forthright in the proposed rule because we treated PBS as though it has been universally recognized as effective.

(Response) FDA disagrees. Citing most of the same literature cited by the commenter, we acknowledged in the proposed rule that positive behavioral approaches may not always be completely successful for all patients, either used alone or in conjunction with pharmacological treatment or other non-ESD treatment options. We also acknowledged that the Panel agreed that positive behavioral approaches alone are not adequate for all individuals who exhibit SIB or AB (81 FR 24386 at 24405 to 24406). Further, we explained that not all providers follow a positive-only behavioral treatment model such as PBS (81 FR 24386 at 24405, citing Refs. 10 and 76). For example, we discussed the sources cited by the commenter that showed success in 52 percent and 60 percent of patients where positive behavioral approaches were attempted and concluded that positive behavioral therapy may sometimes need to be supplemented with pharmacotherapy or other non-ESD treatment options (81 FR 24386 at 24405 to 24406). Thus, FDA has not portrayed PBS effectiveness as an absolute or universally recognized panacea. However, the literature does indicate PBS is successful for many individuals who exhibit SIB or AB and that substantial progress in non-aversive approaches for the treatment of SIB and AB has been evident in the literature for at least 20 years. More recent literature corroborates FDA's position; for example, a recent meta-analysis of case studies in individuals with autism or developmental disabilities and SIB found that 77 percent of subjects had a positive outcome from behavioral interventions for SIB (Ref. 77).

The commenter asserts far more research is needed regarding the efficacy of PBS for SIB and AB, quoting from a literature review that FDA cited in the proposed rule. The review states: "in recent years, a number of questions have been raised regarding PBS, including questions regarding the efficacy of using an exclusively positive approach to support people with seriously challenging behavior" (Ref. 8). Although this article states that further research is needed to validate the findings of the studies conducted, the article goes on to

say its review of 12 published studies concludes that "the results for literally hundreds of individuals who received services in different countries around the world appear to support the conclusion that the (multi-element PBS) model is effective. Specifically, PBS appears to be beneficial for the most severe problems (as well as less severe problems), for high-rate behaviour (as well as low-rate behaviour), and for behaviour problems exhibited by people who live in institutional settings (as well as for people who live in the community" (Ref. 8). FDA agrees more clinical research on PBS would be helpful, but this does not undermine the benefits and general success of PBS that have been shown thus far.

Two sources cited by the commenter that we did not discuss in the proposed rule provide further evidence that state-of-the-art behavioral techniques and psychotropic medications are not always completely effective for all individuals who exhibit SIB or AB, and that further research would be helpful (Refs. 78 and 79). Notably, one of them concludes that outcome measures "suggest a high degree of effectiveness" for behavioral interventions for self-injury (Ref. 79, noting that treatment failures may be underreported). This echoes our explanation in the proposed rule (81 FR 24386 at 24403 to 24410): Although PBS and multielement positive approaches may not be completely effective for every patient, the literature and the experience of experts in the field indicate that these are generally successful, sometimes alongside pharmacotherapy. This is true regardless of the severity of the behavior targeted, there has been substantial progress in non-aversive treatments for SIB and AB, and the success rate for such interventions continues to improve. (See, e.g., Refs. 2, 10, 12, 68, and 80 to 88).

As discussed in the previous comment response, comments on the proposed rule from healthcare providers and experts not affiliated with JRC indicate that positive behavioral interventions are more advanced and effective than described in the proposed rule, and, most importantly, such interventions are very low risk. Based on FDA's expertise, experience, and knowledge of the literature, we agree with the findings of Dr. McCracken, who testified that the majority of this patient population can be successfully treated using a combination of positive behavior supports and pharmacotherapy, without the use of ESDs (Ref. 14, day 9 at 148; day 10 at 107–08).

Lastly, even though there are some patients for whom positive behavioral approaches may not be completely successful, that does not mean ESDs are effective for those patients. As one Panel member stated, the fact that other "therapies are not completely successful or don't work on all patients does not mean, therefore, that electrical aversive stimulation is indicated." See section V.D. for a discussion of ESD effectiveness.

(Comment 44) One comment supports its arguments regarding the ineffectiveness of non-ESD treatment options for certain individuals by asserting that, for the individuals on whom ESDs have been used at JRC, all other behavioral and pharmacological treatment options were attempted and failed.

(Response) FDA has reason to doubt that pharmacological and positive behavioral treatment options were adequately attempted for the individuals on whom ESDs have been used at JRC based on the available data and information from JRC. JRC submitted resident summaries to FDA for 68 individuals at JRC in 2016 on whom ESDs had been used. Of those 68 summaries, only 9 (13 percent) indicate a formal functional assessment was conducted by JRC, and the summaries indicate that 5 other individuals underwent prior assessments at other facilities. JRC also submitted related case conference reports to FDA for 54 of those 68 individuals. Those reports indicate that only 19 individuals (35 percent of 54, 28 percent of 68) had either past or ongoing functional assessments. Therefore, based on the available data and information, only a fraction of individuals at JRC subject to ESDs appear to have undergone functional behavioral assessments.

Further, the resident summaries and conference reports provided to FDA by JRC provide little to no detail regarding the functional assessments that had been conducted. For example, information regarding assessment instruments, granular results, and reassessment results is nonexistent, and in many cases, they do not identify the function of the behavior. Thus, for the minority of individuals who have undergone a documented assessment, the lack of any detail makes it difficult to identify the functions of the target behaviors, corroborate that the assessments met accepted standards, or even that the individuals were periodically reassessed.

In his hearing testimony, JRC's Director of Research, Dr. Blenkush, not only acknowledged that JRC does not perform functional analyses but

recognized that outside observers would question why they have not. (Ref. 14, day 38 at 174). This is consistent with what we explained in the proposed rule: At least some parents who withdrew their children from JRC did not report any activity that would indicate the development of prevention or antecedent strategies, and some reported that facilities their children attended prior to JRC had not attempted such strategies or even conducted FBAs.

As we explained in the proposed rule, a functional behavioral assessment is critical to developing a successful multi-element positive intervention or other empirically derived, individualized behavioral interventions (81 FR 24386 at 24403 to 24404). Failure to conduct a functional behavioral assessment and do so adequately may actually lead to harm because the resulting plan may inadvertently reinforce and consequently increase the problem behavior (Ref. 12). Similarly, inadequately performed functional assessments could reduce the effectiveness of the resulting behavioral intervention (Brown report). The failure to conduct an assessment or re-assessment properly, or even at all, is tantamount to a failure to attempt multi-element positive interventions (*e.g.*, PBS) or other interventions that utilize such assessments.

Further, the resident summaries JRC submitted include diagnoses but do not include any information regarding how primary diagnoses were made, such as what clinical tests or scales were used, or any other information regarding past medical history. Dr. McCracken testified that methods of diagnosing individuals at JRC are outdated, and that its staff “puts very little effort” into properly diagnosing individuals; “the [JRC] clinicians adopted a kind of cut-and-paste mentality from the prior evaluations and appear to not feel the need to more carefully assign and evaluate the presence of these overlapping terms in an effort to understand their clients more deeply.” FDA agrees that JRC’s diagnoses lack thoroughness and careful assessment based on our review of the summaries JRC submitted in its comment. Dr. McCracken further testified, and FDA agrees, that without a proper diagnosis, it is difficult for clinicians to develop an appropriate treatment plan (see Ref. 14, day 9 at 99–101, 104, 107–09, 116–17). As with any medical condition, improper diagnosis, treatment, and lack of access to specialty care limits positive outcomes. A proper diagnosis can greatly increase the chances of beneficial treatment; for example, when comorbid conditions are correctly

diagnosed, they can be successfully treated with psychotherapies, behavioral therapies, and pharmacotherapies that are individualized to the patient’s needs.

With regard to the use of positive interventions prior to ESD use, whether at JRC or before an individual was brought to JRC, the available data and information lack critical details necessary to assess whether these treatments were adequately or appropriately administered. For example, the documents do not provide detail on what specific therapies were attempted, how long they were tried, or what the effects were. We cannot determine from the JRC resident charts and summaries which, if any, treatments were tried prior to placement at JRC. Critically, the documents do not provide enough information to determine whether the interventions were appropriately targeting behaviors, which is necessary to understand whether the interventions failed, and if so, why they failed.

More importantly, these omissions also prevent evaluating whether the use of ESDs caused or contributed to different outcomes. The reasons provided for placement at JRC include not only unsuccessful treatment at previous facilities, but also aging out of previous facilities, rejection by previous facilities, and inability of parents to handle behaviors at home. For some cases, no reason is provided. Dr. Shnidman, a psychologist who wrote reports justifying the use of GEDs on JRC residents as part of the State court approval process, testified that in almost every case, she recommended that the GED was the most effective, least restrictive treatment, yet she was not aware whether JRC tried to use positive interventions or whether positive interventions were effective (see Ref. 14, day 12 at 156, 217). Similarly, Dr. Fox testified that he never saw an individual at JRC for whom an adequate workup had been conducted to establish that a GED was the most effective, least restrictive treatment (see Ref. 14, day 40 at 39).

The JRC resident summaries and the hearing testimony and exhibits that JRC submitted in its comments also cast doubt on JRC’s assertions that pharmacological alternatives were adequately attempted prior to GED use on individuals. For example, the resident summaries excluded information on dosage, regimen (*e.g.*, how many, how often, and for what duration), and both positive and negative effects. In certain instances, the summaries indicate that maximum therapeutic doses were not attempted.

Dr. Mikkelsen testified that many of the medication trials he looked at closely “were inadequate or, you know, the person may only have been on it for two weeks at a low dose and it’s listed as all these medications didn’t work” (Ref. 14, day 7 at 156). Dr. Geller testified that, based on the charts he reviewed for individuals weaned off medication and put on the GED, individuals did not have sufficient trials of psychopharmacology (see Ref. 14, day 21 at 66).

JRC documents indicate that JRC generally opposes the use of pharmacological treatments and makes little effort to attempt their use before or after prescribing the GED for an individual. For example, JRC’s Policy on Psychotropic Medication states, “it is JRC’s policy to avoid, or at least minimize the use of psychotropic medication” and explains that, for individuals on psychotropic medication prior to enrollment at JRC, a psychiatrist will be consulted to consider the benefits of psychotropic medication removal (Ref. 14, exhibit 718). Dr. Joseph, JRC’s sole consulting psychopharmacologist, recommends medication removal in response to almost every JRC referral (Ref. 14, day 40 at 136–37). Once psychotropic medications are eliminated, the individual is typically discharged from Dr. Joseph’s care, and no psychiatrist follows the individual thereafter. In the words of Dr. Geller, Dr. Joseph “sees his task as removing people from all their psychiatric medications and then ending his contact with them” (Ref. 14, day 21 at 66). Of the 64 individuals with a treatment plan including ESD use as of June 2015, 7 had no record of any psychopharmacological consultations, 50 had not had psychopharmacological evaluations for over 5 years; of these 50, 37 had not had psychopharmacological evaluations for over 10 years, and 8 had not had psychopharmacological evaluations for over 20 years (Ref. 14, day 21 at 6–9, referring to impounded exhibit 662).

Other comments and testimony indicate that non-ESD alternatives have been or likely would be successful for individuals on whom ESDs have been used at JRC. Several comments from healthcare providers explain that patients with severe SIB or AB at JRC present behaviors that are challenging to treat. However, such behaviors are no more challenging to treat than those exhibited by patients with similar conditions who are successfully treated across the country without the use of ESDs. This is supported by fact and expert witnesses in the hearing testimony cited by JRC, who testified

that individuals with the most challenging SIB and AB have been successfully treated without the use of skin shock at various institutions across the country. (See, e.g., Ref. 14, day 4 at 42–43 (Simons); day 7 at 49, 60–61, 181 (Mikkelsen); day 9 at 39–40, 160 (McCracken); day 13 at 11–12, 138 (Zarcone); day 14 at 24, 28 (Thaler).)

For example, Dr. McCracken, a clinician who treats individuals with developmental disabilities who engage in SIB and AB, testified that his clinic has been successful in treating the vast majority of individuals and has been able to help everyone, at least to some degree, without using skin shock (Ref. 14, day 10 at 107–08). Dr. Alfred Bacotti, another clinician, testified that in his 30 years as a psychologist treating patients, including some with SIB and AB as severe as those exhibited by JRC residents, he never used skin shock (Ref. 14 at 212). Perhaps most tellingly, Dr. Chris White, a licensed psychologist with over 30 years of experience in the field of behavioral therapies who runs a facility to which many individuals formerly on ESDs at JRC were transferred, testified at a Massachusetts DDS hearing in 2011 that his facility has been able to successfully serve these individuals without the use of aversives by taking a combined-treatment approach, emphasizing positive interventions. (See Ref. 14, exhibit 455, at 142–43, for a partial transcript of the July 2001 hearing.)

(Comment 45) Behavioral therapists comment that state-of-the-art treatments such as PBS can prevent the recurrence of SIB and AB because they address the underlying causes of SIB and AB and the communicative needs of patients, unlike ESDs.

(Response) FDA agrees that state-of-the-art interventions such as PBS are generally successful because, unlike ESDs, they address the underlying causes of SIB and AB. As we explained in the proposed rule, one goal of state-of-the-art approaches such as PBS is to teach new behaviors that proactively displace undesirable behaviors (SIB and AB) by teaching individuals to express themselves with behavioral substitutions that will not cause harm to themselves or others (Refs. 87 and 89). For example, functional communication training, as one element of an intervention, examines the communicative intent of the problem behaviors (what the individual is trying to communicate or obtain from others), and then focuses on teaching the individual a functionally equivalent, but non-problematic, behavior (Ref. 12). There has been a shift toward prevention in recent years (e.g.,

structured environment and schedule, support services at school), and prevention of SIB and AB is considered the best practice, particularly for those with intellectual and developmental disabilities (Refs. 77 and 90).

In contrast, as these comments point out, the use of ESDs does not teach a person new skills or replacement behaviors, does not mitigate the underlying cause, and cannot achieve behavioral conditioning for some patients who have conditions that impair their ability to understand consequences and react by changing their behaviors (Ref. 8). Even Dr. Blenkush of JRC stated that providers there can reduce the use of ESDs through skill training or other procedures and that even people whom JRC thought could not be faded off of ESDs responded to these treatments (Ref. 15 at 148). These are some of the reasons that the field of ABA as a whole moved away from intrusive physical aversive conditioning techniques such as ESDs two decades ago (Ref. 9, reprinted from 1990, and Ref. 91).

(Comment 46) Some parents of individuals at JRC who exhibit SIB or AB comment that ESDs have been the only treatment capable of reducing their family member's behaviors. They argue that a ban on ESDs for SIB or AB would force them to resort to ineffective and risky therapies such as restraints and medication. Another comment states that FDA has dismissed such parents' views on the basis that a very small minority claimed they were coerced or misled.

(Response) FDA has not dismissed the views of these parents but rather has given their input careful consideration. As we stated in the proposed rule, FDA has no reason to doubt these parents' best intentions, the sincerity of their belief that an ESD is the best or perhaps only option for their loved one, or that they have tried alternatives without success. Whether they were opposed to or in favor of a ban, FDA considered each parent's comments and submissions for the Panel Meeting, as well as their comments submitted to the public docket for this rule. As explained in the proposed rule, we did not consider these parents' reports as scientific evidence relating to the use of the devices. Rather, FDA used these parents' reports to help inform our understanding of parents' and patients' experiences and knowledge regarding the risks and benefits of ESDs and the state of the art.

As explained in the proposed rule, FDA has reason to question the information provided to family members by JRC. We explained how

some of the parents' reported experiences contradicted assertions that the devices were only used as a last resort and indicated that other treatment strategies were not adequately attempted, in which case it is not known whether they would have been successful. In the proposed rule, we referred to parents' reports that, for some of their children, schools did not attempt all treatment options. For example, some schools did not use a functional behavioral assessment to develop prevention or antecedent strategies, strategies that are hallmarks of state-of-the-art interventions (81 FR 24386 at 21409). Ref. 92 also stated that once the family members were at JRC, none of the parents reported the development of prevention or antecedent strategies. None of the comments on the proposed rule cause us to view these reports differently. Taken together, these parents' reports indicate that non-ESD interventions based on functional behavioral assessments that seek to prevent target behaviors were not adequately attempted for these individuals. As we acknowledged in the proposed rule, we understand that these reports are only from certain parents who volunteered to share negative experiences, and we cannot conclude that these reported experiences were shared by others or are generally representative of families' experiences at JRC.

As with the parents of individuals at JRC, we have no reason to doubt the sincerity of the parents who removed their children from JRC. As one researcher noted, these individuals and their families "have likely traveled a rough path" (Ref. 12). For these individuals, ESDs were not in fact applied as a last resort, and their parents reported feelings of coercion from JRC (Ref. 92). It thus appears that at least some parents felt pressured to agree to the use of ESDs, and for at least some individuals, alternative treatments were not exhausted.

One comment asserts these viewpoints are hearsay and criticizes FDA for relying on them while elsewhere rejecting articles supporting ESD effectiveness because they are not deemed adequately controlled studies. This criticism is without merit. In fact, FDA's views regarding the exhaustion of behavioral and pharmacological treatment options are informed primarily by the scientific literature regarding state-of-the-art treatments for SIB and AB, expert views on these issues, and the records provided by JRC regarding individual treatment prior to ESD use, which suffer from serious limitations, as discussed in Responses

38 and 44. FDA also considered the views and experiences of parents; as they relate to the current state of medical practice and alternative treatment attempts, the reports from parents who oppose the use of ESDs are consistent with the data and information we considered and explained in the proposed rule as well as the records JRC provided regarding its residents. Further, the vast majority of parents who commented on the state of the art opposed the use of ESDs.

Again, evidence of failures of treatments other than ESDs is not evidence that ESDs safely or successfully treat patients. Programs across the nation successfully treat SIB and AB without ESDs. While some parents may sincerely believe in the necessity of ESDs and undoubtedly face serious difficulties in selecting treatment, their information may be incomplete, and alternatives may not have been adequately attempted.

(Comment 47) Hundreds of parents of individuals who exhibit SIB or AB comment that positive-only approaches work even for the most severe manifestations of SIB or AB. Some describe a need to be supportive of individuals, contrasting support with the physically punitive nature of ESDs.

(Response) These comments are consistent with FDA's finding that the state of the art for the treatment of SIB or AB relies on multielement positive methods, especially PBS, sometimes in conjunction with pharmacological treatments. "Positive" can apply to many different treatment modalities, but it does not include aversive interventions such as contingent skin shock (Refs. 9 and 70). State-of-the-art, multielement, positive interventions such as PBS rely on functional behavior assessments to design a treatment plan for individual patients.

Clinicians ordinarily try multiple positive treatment interventions if the initial treatment is not successful. Indeed, if a given intervention does not reduce or eliminate an unwanted behavior, a clinician would adjust the treatment on an empirical basis. As one expert in PBS explained, the assessment of behaviors and design of interventions is an iterative process, and continual adjustment of positive interventions will serve the patient better than substituting elements with the use of ESDs (Ref. 82). FDA believes that what these parents describe in their comments mirrors the state of the art for the treatment of SIB or AB. Multielement positive interventions are designed to support the individual by teaching skills and replacement behaviors, and such interventions can

achieve durable success in community and home settings (Refs. 12, 87, and 88).

(Comment 48) Comments assert that punishment generally, contingent shock, and the use of ESDs are state-of-the-art treatment options for patients with SIB and AB (along with PBS, pharmacotherapy, and restraint).

(Response) To ban a device under section 516 of the FD&C Act, FDA must find that it presents substantial deception or an unreasonable and substantial risk of illness or injury. As we explained in the preamble to the proposed rule, with respect to 'unreasonable risk,' we will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users. The state of the art with respect to this proposed rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior. Thus, in determining whether a device presents an 'unreasonable and substantial risk of illness or injury,' FDA analyzes the risks and the benefits the device poses to individuals, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice (81 FR 24386 at 24386 to 24388).

The purpose of the analysis of the state of the art is to assess the risks and benefits of alternatives used in current medical practice to treat a particular patient population and to compare those to the risks and benefits of the device that is the subject of the ban, not to determine whether the device that is the subject of the ban is part of the state of the art. For these reasons, whether punishment, contingent shock, or ESDs are within the standard of care or state of the art is not an issue in this rulemaking. However, the state of current technical and scientific knowledge and medical practice with regard to the use of punishment generally and ESDs in particular on patients exhibiting SIB and AB may still bear some indirect relevance to the risk-benefit profile of ESDs as compared to alternative treatments.

As we explained in the proposed rule, punishment techniques include a broad range of consequences (81 FR 24386 at 24405 to 24406). On one end of the spectrum, some are highly restrictive and/or painful, such as the use of ESDs or food deprivation, while, on the other end, some are less or non-intrusive, such as using "time-outs." Given such a broad range, FDA did not attempt to define all possible punishment techniques relative to the state of the art.

During the hearing, Dr. Zarcone testified that she uses punishment techniques such as time-outs, holds, and facial screening. However, she said that she distinguishes her techniques from those that cause pain such as the use of ESDs (Ref. 14, day 15 at 31–41). Her techniques are less intrusive, and in her view, teach the individual something about the behavior and are effective. Such techniques can be compatible with PBS. In contrast, painful punishments, including aversive interventions, are not compatible (Ref. 14, day 13 at 103–04). One textbook explains that electric shock can be replaced with "more acceptable aversive outcomes" such as a squirt of lemon juice or a reprimand (Ref. 59 at 56–79). Similarly, Dr. Daniel Bagner, a clinician and professor, testified that he does not teach parents to use painful punishment such as electric shocks or spanking, and that such techniques are not part of any evidence-based treatment (Ref. 14, day 11 at 81).

While punishment-based techniques may appear in textbooks that provide an overview of treatments for completeness, such references often caveat the use of punishment-based techniques as less beneficial than others. As we stated in the proposed rule, a 2008 survey of the members of the Association for Behavior Analysis found that providers generally view punishment procedures as having more negative side effects and being less successful than other reinforcement procedures (Ref. 76). The study of punishment to treat SIB and AB peaked in the 1980s and has been declining steadily ever since (Ref. 93).

Regarding ESDs, as we explained in the proposed rule, researchers have long raised ethical concerns about purposefully subjecting patients to the harms caused by physically aversive stimuli (see, e.g., Refs. 9, 60, 66, 71, and 88). Review of the current scientific literature confirms that, in recent decades, medical practice has shifted away from restrictive physical aversive conditioning techniques such as ESDs and toward treating patients with SIB and AB with positive-based behavioral interventions (see, e.g., Refs. 9, 10, and 91; see also 81 FR 24386 at 24405). Indeed, of the 57 total published studies on the effectiveness of contingent skin shock, only 10 such studies have been published in the past 20 years, and only 1 in the past decade. Although a few ABA textbooks (one of which is authored by a JRC Board member) mention contingent skin shock as an available technique, they also emphasize the highly limited use of ESDs due to negative side effects and

ethical and humanitarian objections (Ref. 94). FDA acknowledges that a number of States do not prohibit the use of ESDs for SIB or AB on their residents, and some States reimburse individuals for the use of ESDs on their residents in certain circumstances. However, according to a 2015 survey conducted by NASDDDS, 37 of the 45 States that responded reported that aversive interventions are disallowed for treatment of people with intellectual or developmental disabilities, and none of the other eight States included ESDs as permissible aversives. With regard to the GED specifically, Dr. McCracken testified that no valid evidence supports the use of the GED and that its use is unethical (Ref. 14, day 9 at 79, 85–86, 160).

Perhaps most revealingly, as JRC acknowledges in its comments, JRC is currently the only facility in the country that uses ESDs for SIB or AB, and it uses ESDs on individuals from only 12 States.

(Comment 49) A comment questions FDA's reliance on expert reports for the proposed rule because the experts are vocal advocates for PBS and vocal critics against the use of ESDs. The comment argues that FDA sought to bolster a particular point of view with biased advocates rather than seek information in a more neutral way, and that FDA did not similarly defer to the opinions of experts affiliated with the manufacturer.

(Response) FDA disagrees. Although two of the three outside experts from whom FDA solicited reports oppose the use of ESDs and support the ban, the third, Dr. Smith, opposes the ban and instead argues in his report for allowing their continued use with new regulatory restrictions. In the proposed rule, we made clear these reports are "solicited opinions." The fact that we found the views of some experts more compelling than others does not mean we deferred to some and dismissed others. Rather, given their expertise and experience, we considered the opinions of all three experts in our analysis of the risks and benefits of ESDs and alternative treatments, similar to our consideration of the expert views of the Panel members. In evaluating these views, we took into account any potential biases, similar to our review of the literature. FDA made these solicited opinions and the transcript of the Panel Meeting publicly available in the docket for the proposed rule, so commenters had an opportunity to examine and respond to them.

(Comment 50) One comment asserts that there are no pharmacologic treatments specifically approved for

treatment of SIB and AB; thus, no drug has been proven effective for such uses, such uses are off-label, and no drug should be considered a state-of-the-art treatment for SIB or AB. The comment further asserts that pharmacotherapy is ineffective for some patients and has severe risks.

(Response) FDA disagrees with the assertions that state-of-the-art treatments for SIB or AB do not include

pharmacotherapy, and that there are no pharmacologic treatments specifically approved for the treatment of SIB or AB.

It is important to understand that SIB and AB are not disorders themselves but rather symptoms associated with various underlying conditions. In clinical practice, SIB and AB are referred to as transdiagnostic symptoms because they can be associated with numerous, sometimes comorbid conditions and are not specific to a particular diagnosis. Examples of disorders in which patients may exhibit SIB and AB include, but are not limited to:

- Psychiatric disorders, which have a relatively high prevalence of SIB and AB, for example, attention deficit hyperactivity disorder (ADHD), mood disorders, psychotic disorders, PTSD, eating disorders, anxiety disorders, adjustment disorders, and substance use disorders;

- neurodevelopmental disorders (NDDs) and genetic disorders, which also have a relatively high prevalence of SIB and AB, for example, ASD (the definition of which was recently broadened in the DSM–5), stereotypic movement disorder, intellectual disability, Lesch-Nyhan Syndrome, fragile X syndrome, Angelman Syndrome, and fetal alcohol syndrome (FAS); and

- medical diagnoses, for example, traumatic brain injury, cerebral palsy, and sleep disorders.

The comment incorrectly minimizes the importance of proper diagnosis and treatment of underlying causes of SIB and AB. Treatment of moderate to severe SIB and AB is complex and should be tailored to the individual needs of each patient; treating the underlying condition often improves SIB and AB symptoms. Therefore, state-of-the-art treatment for SIB and AB begins with a proper diagnosis, obtained using a comprehensive psychiatric and medical examination by a board-certified specialist (e.g., psychiatrist) in consultation with other professionals, such as psychologists, pediatricians or internists, and neurologists (Ref. 95). In recent years, advancements in psychiatric research and clinical care have improved our understanding of

psychiatric diagnosis and treatment, particularly in individuals with intellectual and developmental disabilities. This has facilitated the use of pharmacological treatments that reduce SIB and AB, whether the drug products target SIB or AB symptoms directly, regardless of the underlying condition, or by more indirectly reducing SIB and AB by improving the underlying condition.

The prevalence of SIB in NDD is high, as high as 50 percent in ASD (Ref. 96), a population representing a subset of all patients with SIB and AB. Two drugs are approved for treating irritability associated with ASD, one of which specifically includes SIB and AB among its approved indications. Specifically, RISPERDAL (risperidone) is FDA-approved for the treatment of "irritability associated with autistic disorder, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods," (emphasis added).⁸ As described in the proposed rule, ABILIFY (aripiprazole), has also been approved by FDA for the treatment of irritability associated with autistic disorder in children. As explained in the FDA-approved labeling for ABILIFY, "The efficacy of ABILIFY (aripiprazole) in the treatment of irritability associated with autistic disorder was established in two 8-week, placebo-controlled trials in pediatric patients (6 to 17 years of age) who met the DSM–IV criteria for autistic disorder and demonstrated behaviors such as tantrums, aggression, self-injurious behavior, or a combination of these problems," (emphasis added).⁹ Both ABILIFY (aripiprazole) and RISPERDAL (risperidone) met their primary efficacy endpoint by demonstrating statistically significant changes in score on the Aberrant Behavior Checklist—Irritability scale (ABC–I), which is one of the most commonly used scales to measure SIB and AB in drug development programs. Thus, the comment is incorrect that no drugs have been proven effective for SIB and AB in any population.

To date, most of the randomized clinical trials completed for the treatment of SIB and AB have been conducted in youth with developmental disabilities such as ASD (see Ref. 77 for review). In clinical practice, results from these clinical trials for the treatment of SIB and AB in ASD inform state-of-the-

⁸ Labeling available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020272s082,020588s070,021444s0561bl.pdf.

⁹ Labeling available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021436s043,021713s034,021729s026,021866s0281bl.pdf.

art pharmacotherapy for SIB and AB treatment across diagnoses because SIB and AB are considered transdiagnostic symptoms. Therefore, clinicians consider data related to treatment of SIB and AB in ASD when determining whether to prescribe drugs for the treatment of SIB and AB in other psychiatric, genetic, medical and neurodevelopmental disorders in children and adults.

The comment recognizes that “pharmacotherapy may be effective in controlling the behaviors of certain patients.” The comment’s main concern seems to be that, “pharmacotherapy is not uniformly effective,” or that “these types of drugs are not effective for all persons that exhibit aggressive and SIB behavior.” FDA agrees that risperidone and aripiprazole are not uniformly effective for the treatment of SIB and AB in all patients. However, this does not undermine FDA’s conclusion that the literature indicates that positive behavioral interventions, sometimes alongside pharmacotherapy, are generally successful for the treatment of SIB and AB, regardless of the severity of the behavior targeted.

The comment highlights the side effects that drugs used to treat SIB and AB can cause, some of which can be severe. For example, as FDA pointed out in the proposed rule, the most common adverse reactions observed in the trials conducted for approval of RISPERDAL and ABILIFY were sedation, increased appetite, fatigue, constipation, vomiting, and drooling. Other less common serious adverse reactions with the use of risperidone or aripiprazole may include neuroleptic malignant syndrome, gynecomastia, galactorrhea, metabolic changes, and tardive dyskinesia (note, valbenazine (INGREZZA) and deutetrabenazine (AUSTEDO) have been approved for the treatment of tardive dyskinesia). FDA acknowledges the significance of the risks posed by pharmacotherapy, but assesses them together with their proven benefits. FDA determined that the benefits outweigh the risks in the population for which they are intended when we approved these drugs for irritability associated with ASD based on well-controlled clinical studies.

Further, drugs that have not been approved for treatment of SIB and AB and thus have not been found safe and effective for this use may nonetheless be part of state-of-the-art treatment for SIB and AB, which has a specific meaning in the context of a device ban. As we explained in the preamble to the proposed rule, and maintain now, the state of the art with respect to this proposed rule is the state of current

technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior (81 FR 24386 at 24388). Elsewhere in its comments, the commenter recognizes that state-of-the-art treatment for this patient population can include pharmacotherapy, among other options, and asserts that a wide range of pharmacological interventions have been used to treat patients with SIB and AB, including mood stabilizers, antidepressants, and antipsychotics.

A systematic review was recently completed of randomized, placebo-controlled studies that measured the effect of pharmacologic treatments on reduction of aggressive behaviors and irritability, measured using the ABC-I change from baseline score in children with ASD (Ref. 97). Ref. 97 reports improvement on ABC-I scores for numerous drugs, including risperidone (Cohen’s $d = 0.9$), aripiprazole ($d = 0.8$), clonidine (Cohen’s $d = 0.6$), methylphenidate ($d = 0.6$), venlafaxine ($d = 0.4$), naltrexone ($d = 0.35$), and valproate ($d = 0.3$). Ref. 97 illustrates that several drugs in addition to risperidone and aripiprazole have evidence-based support suggesting that they can improve symptoms of SIB and AB in ASD. As noted above, only risperidone and aripiprazole have FDA approval for the treatment of irritability in ASD.

In evaluating the state of the art for purposes of determining whether to ban ESDs, FDA considered the available information regarding risks of these drugs used for SIB and AB, as well as the available information regarding their benefits in treating SIB and AB symptoms. The general risks of risperidone, aripiprazole, clonidine (an alpha-agonist), and methylphenidate (a stimulant) are described elsewhere in this comment response. Common adverse reactions associated with serotonin-norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine include headache, insomnia, diarrhea, vomiting, decreased appetite, hyperactivity, irritability, sexual dysfunction, muscle pain, and change in weight; mania, abnormal heart rhythm, and suicidal ideation and behavior can also occur. Valproate has FDA-approved indications in adults related to bipolar disorder, seizures, and migraine headaches. Common side effects include somnolence, dyspepsia, nausea, vomiting, diarrhea, dizziness, and pain. Serious adverse reactions can occur, including hepatotoxicity, fetal malformations, multiorgan hypersensitivity reactions, and thrombocytopenia. Naltrexone is an

opioid antagonist approved for the treatment of addiction and is associated with dyspepsia, diarrhea, nervousness, sleep problems, muscle pain and can cause liver injury and allergic pneumonia.

As stated previously, other drugs may improve SIB and AB symptoms by treating the underlying disorder for which they are approved. Thus, in considering the state-of-the-art treatment for SIB and AB, FDA also considered these treatments of underlying disorders. For example, children who are impulsive with aggressive outbursts may have moderate to severe ADHD. FDA-approved medications can treat symptoms of ADHD, including impulsivity, and therefore may also reduce associated SIB and AB symptoms. FDA-approved medications for ADHD include stimulant and non-stimulant medications. Stimulants include amphetamine and methylphenidate drugs. Common adverse reactions with stimulant use include decreased appetite, trouble falling asleep, irritability, headaches, and stomachaches. Reduction in growth rate, sadness, irritability, tics, abuse, dependence, and elevation in blood pressures and heart rate can also occur. Sudden death, stroke, and myocardial infarction have been reported in otherwise healthy adults and in youth with heart problems taking stimulants. Non-stimulants with FDA-approval for ADHD include atomoxetine and alpha-agonists. Adverse reactions to non-stimulant medications include tiredness, insomnia, stomachaches, headaches, and nausea; hepatitis and suicidal thoughts can also occur. Thus, these drugs are not without risks, although in approving them, FDA determined that their risks are outweighed by their benefits in treating ADHD.

Accurate diagnosis is especially important for mood disorders because choosing the wrong class of medications for treatment may worsen SIB or AB symptoms. For example, individuals who have bipolar disorder can be misdiagnosed with depression, especially children and adolescents. This is important because prescribing antidepressant medications to patients with bipolar disorder may induce or worsen symptoms of mania, which may include symptoms of irritability and impulsivity, both of which can be associated with SIB or AB. Medications approved to treat bipolar disorder include atypical antipsychotics, anticonvulsants, and lithium salts. Risks associated with these medications include but are not limited to sedation,

metabolic changes, rash, and other cardiovascular, endocrine, hematopoietic, and neurological adverse reactions. Neuroleptic malignant syndrome, extrapyramidal symptoms, tardive dyskinesia, and gynecomastia/galactorrhea can also occur.

Some congenital and genetic disorders are also associated with SIB and AB symptoms. Advancements in understanding genetic and prenatal exposure-related causes for intellectual and developmental disabilities have improved diagnosis and management of these conditions, for example through genetic testing. This is important because some genetic disorders have treatments, some of which are pharmacological, that can improve the underlying condition and may also improve associated behavioral problems such as SIB and AB. For example, psychiatric and behavioral symptoms associated with phenylketonuria (PKU) can improve with diet or medications such as pegvaliase-pqpz, which received FDA approval for the treatment of PKU in 2018 (Ref. 98). The most common adverse reactions occurring in at least 15 percent of patients taking pegvaliase-pqpz were injection site reactions, arthralgia, hypersensitivity reactions, headache, pruritus, nausea, and dizziness.

Finally, we now recognize that individuals with NDDs, intellectual disabilities, and other developmental disabilities can have comorbid psychiatric conditions that benefit from treatment. For example, treatment of comorbid depression, anxiety, ADHD, psychosis, or bipolar disorder, can improve symptoms such as irritability, psychomotor agitation, impulsivity, and worthlessness, which, in turn, can attenuate associated SIB and AB symptoms. As Dr. McCracken testified at the Massachusetts hearing, psychiatrists now recognize that developmentally disabled individuals are at high risk for a variety of psychological disorders and it is generally accepted medical practice to treat co-morbid disorders in individuals who exhibit challenging behaviors (Ref. 14, day 9 at 93). Patients and healthcare providers have numerous medication options to treat comorbid psychiatric diagnoses and the associated symptoms, as described earlier in this comment response.

F. Labeling and Correcting or Eliminating Risks

(Comment 51) Some comments argue that the risks associated with ESDs for SIB or AB can be corrected or eliminated through labeling and other controls, such as the labeling and

process JRC currently uses prior to using ESDs on an individual.

(Response) FDA disagrees. FDA considered all available data and information, and we have determined that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury. Regardless of how the device is labeled, the individual subject to it will receive shocks intended to be painful and will continue to be subject to the physical and psychological risks we have described in this rulemaking. No manner of labeling will correct or eliminate these risks, so the device will continue to present the same unreasonable and substantial risk of illness or injury. The commenter does not offer any alternative except to limit the number of vulnerable individuals subject to the unreasonable and substantial risk.

The Panel members who opined that the banning standard is met (a majority of the Panel) were asked whether labeling could correct or eliminate the risk of illness or injury posed by ESDs and all concluded that labeling could not correct or eliminate the dangers associated with ESDs. As we explain in Responses 14 and 18, factors outside of the user's control, including the psychological state of the individual subject to the device, can play a significant role in how an individual perceives any given shock or series of shocks. Further, especially for those with intellectual or developmental disabilities, the individual may not communicate or be able to communicate information for the device user to change the manner in which the device is used to correct or eliminate the risks. Because these factors are outside of the user's control or are difficult to ascertain or predict, labeling that corrects or eliminates the risks of ESDs for SIB or AB cannot be written.

The only labeling suggestion the commenter offers regards labeling the device for use only in individuals refractory to other treatments, which is how JRC's GED devices are currently labeled. As explained in comment Response 30, if such a subpopulation does exist, it is very difficult to define. Even if such a subpopulation could be identified, specifying this limitation in the labeling would not correct or eliminate the risks for those individuals. Further, as discussed in the comment responses regarding effects, no subpopulation has been identified in which ESDs are more likely to be effective, and thus the risks of ESDs would still outweigh the benefits. Similarly, as recognized by the Panel members who were asked, limiting the

indications to a subpopulation of individuals who engage in life-threatening behaviors would not mitigate the risks for those individuals, and there is no evidence that the device is effective in such a subpopulation. Accordingly, limiting the use of the device to a narrower population through labeling would also not correct or eliminate the risks.

(Comment 52) A comment argues that general "treatment resistant" language adequately defines the population for whom ECT devices are intended, which is precisely the population on whom JRC uses ESDs, and which language could be used in ESD labeling to limit the device's use to individuals who are refractory to all behavior controls except ESDs.

(Response) FDA acknowledges that there is language regarding treatment resistance that does not precisely define a refractory subpopulation in the labeling for certain other devices that have different intended uses and different intended patient populations. However, FDA's position is not that imprecise descriptions of a refractory patient population are necessarily inadequate but rather that, in the case of ESDs used for SIB or AB, labeling stating that the device should only be used in a refractory subpopulation would not correct or eliminate the unreasonable and substantial risk of illness or injury to that population. This is because in the case of ESDs, the available data and information do not establish that the devices are effective for treating SIB or AB in people who are refractory to other approaches. Thus, given that the serious risks posed by ESDs for SIB or AB apply to refractory patients just as they do to others, the risks of this device outweigh its benefits regardless of whether other options may have been attempted, and labeling limiting its use to a refractory population would in no way change this. In contrast, for ECT, the available data associated with its use, including in treatment resistant patients, was of better quality and provided a reasonable assurance of safety and effectiveness.

Further, for ECT there are better-defined hierarchies of treatment options prior to use of ECT, based on data demonstrating instances where other appropriate treatment options were tried and failed. For example, the APA has issued recommendations for determining when the use of ECT may be appropriate (Ref. 99), as has the National Institute for Health and Clinical Excellence in the United Kingdom (Ref. 100). Thus, the use of "treatment resistant" language for ECT, in light of the data and the formal,

evidence-based practice guidelines, reflects a much clearer consensus than is available for the use of ESDs for SIB or AB. As discussed in earlier comment responses, it is difficult to define a refractory population for ESDs for SIB or AB, JRC has not established that its residents on whom ESDs are used are refractory to other treatments, and the evidence shows that state-of-the-art alternatives have generally been successful even for the most difficult cases. Accordingly, ECT is distinguishable and FDA's determination remains that labeling or a change in labeling cannot correct or eliminate the substantial and unreasonable risks of illness or injury of ESDs used for SIB or AB.

(Comment 53) A comment argues that an expert believes labeling can be developed to minimize the risks of ESDs. The comment refers to an expert whose opinion FDA solicited regarding this ban.

(Response) FDA disagrees. Dr. Smith proposed certain restrictions, but none of these address labeling.

G. Legal Issues

(Comment 54) One commenter suggests that the evidentiary standard for banning a device is a "preponderance of evidence," meaning that there must be proof of harm and not just theoretical risk. The commenter bases this on a statement in the proposed glove powder ban that the preponderance of evidence suggests that use of an alternative reduces the incidence of certain harms (81 FR 15173, 15179, March 22, 2016).¹⁰

(Response) FDA disagrees. As Congress explained in the legislative history of section 516 of the FD&C Act, and as FDA stated in the preamble to its banning regulations at 21 CFR part 895 and in the preambles to the proposed rules to ban ESDs and glove powder, actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information. H. Rep. 94-853 at 19; 44 FR 29214 at 29215; 81 FR 15173 at 15176; 81 FR 24386 at 24392. The proposed rule to ban glove powder does not state otherwise. The statement cited by the commenter does not address the standard for a device ban, nor does it imply that actual harm is required to meet the standard; it simply states that the evidence relevant to that proceeding indicated that using alternatives would

more likely than not result in lower frequency of certain harms relative to glove powder.

(Comment 55) One commenter claims that FDA arbitrarily and capriciously discounted JRC patient data in the proposed rule and instead relied on data that are anecdotal and that were carefully selected to support the Agency's position.

(Response) FDA disagrees. As discussed in sections III.A. and V.B., FDA considered all available data and information, including anecdotal information, and weighed it appropriately in making our decision. FDA provided multiple opportunities for input from all stakeholders and notes again that the expert Panel also weighed all available evidence, applied its expertise and a majority supported a ban.

(Comment 56) Commenters argue that FDA does not have authority to ban a device for a specific use or uses, but rather must ban a device for all uses. One of these commenters argues banning a device only for certain uses is inconsistent with section 513(i)(1)(E) of the FD&C Act, and another claims FDA's only previous device ban at the time banned implanted all hair fibers without regard to their intended uses.

(Response) FDA disagrees. There is nothing in the FD&C Act or its implementing regulations that requires a ban under section 516 of the FD&C Act to apply to all uses of a device. To the contrary, it is difficult to conceive of a ban of a device divorced from its intended use since devices are defined and regulated not only according to their technological characteristics but also according to their intended uses. See, e.g., section 201(h) of the FD&C Act and the device classification regulations at 21 CFR parts 862 through 892. Thus, a device may be one class for one use and a different class for another use, see, e.g., 21 CFR 886.5916 (rigid gas permeable contact lens, class II if intended for daily wear, class III if intended for extended wear). This is clearly what Congress intended. See H.R. Rep. No. 94-853 at 14-15 (Feb. 29, 1976) ("Finally, despite the fact that generally the term 'device' is used in the bill to refer to an individual product or to a type or class of products, there may be instances in which a particular device is intended to be used for more than one purpose. In such instances, it is the Committee's intention that each use may, at the Secretary of Health and Human Services' (Secretary) discretion, be treated as constituting a different device for purposes of classification and other regulation."). Similarly, a product may be regulated as a "device" for one

intended use, or, if it had a different intended use, it may be regulated as a "drug" (e.g., if it achieved its primary intended purposes through chemical action in or on the human body).

As discussed earlier, in determining whether a device presents an unreasonable and substantial risk of illness or injury, FDA weighs the device's benefits against its risks and considers the risks relative to the state of the art; the benefits and risks of a device and the state of the art are heavily impacted by the device's intended uses, including the patient population for whom it is intended. Thus, FDA's banning regulation for prosthetic hair fibers explains that these devices are intended for implantation into the human scalp to simulate natural hair or conceal baldness, 21 CFR 895.101, and the glove powder ban is not for any gloves or powder but, for certain powdered gloves intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination and intended for medical purposes, that are worn on the examiner's hand or finger to prevent contamination between patient and examiner, and glove powder intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove (21 CFR 895.102, 895.103, and 895.104).

The commenter's reliance on section 513(i)(1)(E) of the FD&C Act is misplaced for several reasons. First, this provision only pertains to review of a 510(k) and not to device bans or any other aspect of device regulation. Second, if the commenter's point is that harmful uses of a device should not prohibit its beneficial uses, this cuts against the commenter's position that FDA must ban a device for all uses. FDA is only banning ESDs for certain uses, which is consistent with the principles underlying section 513(i)(1)(E) of the FD&C Act. Third, if the commenter's point is that FDA should not prohibit use of a device that may be harmful if labeling can adequately mitigate such harm, the harmful uses of ESDs are its labeled uses, not ones outside the labeling, which are the target of section 513(i)(1)(E). Further, section 516 of the FD&C Act and its implementing regulations only authorize banning where FDA has determined the deception or risk cannot be corrected or eliminated by labeling, as FDA has done here; this is also consistent with the principles underlying section 513(i)(1)(E) of the FD&C Act.

(Comment 57) Commenters assert that the proposed ban on ESDs would interfere with the practice of medicine and the doctor-patient relationship, specifically with respect to doctors and

¹⁰ Available at <https://www.federalregister.gov/documents/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and>.

patients at JRC, in contravention of section 1006 of the FD&C Act (21 U.S.C. 396). One of these comments recognizes that what it refers to as the practice of medicine exemption does not limit FDA's ability to determine which devices are available to prescribe but argues that it means FDA cannot ban one use of a device and not others.

(Response) FDA disagrees. Section 1006 of the FD&C Act states that nothing in this act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This makes clear, for example, that a doctor may prescribe an approved device for a use different from those for which it has been approved; it does not, however, in any way limit FDA's ability to determine which devices can be legally marketed and the uses for which they can be legally marketed. Indeed, the next sentence of section 1006, not cited by these commenters, explains that this section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or issued through regulations. Banning ESDs for SIB or AB would not violate section 1006 of the FD&C Act or be inconsistent with its general approach toward the practice of medicine. Pursuant to this ban, ESDs for SIB or AB, such as the GED devices manufactured and used at JRC, are adulterated under section 501(g) of the FD&C Act, and thus are not legally marketed devices. FDA's issuing of this rule in no way conflicts with section 1006 of the FD&C Act or FDA's long-standing position regarding the practice of medicine.

(Comment 58) One commenter argues that FDA does not have the authority to determine the state of the art and decide that one therapy is appropriate and another is not, and that in doing so FDA is playing the role of doctor, which sets a dangerous precedent that would allow FDA to ban any device or use of any device any time it disagrees with clinical practice.

(Response) FDA disagrees. As explained in the preamble to FDA's banning regulations, in determining whether a device presents an unreasonable risk, we should assess the device's risks relative to the state of the art. Before banning a device, it is thus important to consider the current state of science and medicine relevant to the device and the patient population the

device is intended for, including alternative treatments. This does not mean FDA is "playing the role of doctor" any more than it does when FDA decides whether to approve a medical product; in both contexts FDA must determine whether the applicable statutory standard is met.

(Comment 59) One commenter argues that because these devices were manufactured years ago, the ban is only about the use of the device.

(Response) FDA disagrees. As discussed above, a device is defined in terms of both its technological characteristics and its intended use(s). As discussed in section III, the ban prohibits future manufacturing and distribution or sale of ESDs for SIB or AB by anyone, and the ban also applies to any such devices already manufactured and being held for sale, such as the GEDs in use at JRC.

(Comment 60) In the context of its arguments regarding the practice of medicine, one commenter cites section 510(g) of the FD&C Act and 21 CFR 807.65(d), which exempt practitioners licensed by law to prescribe or administer devices and who manufacture devices solely for use in their practice from registration and listing, and consequently, premarket notification, requirements. The commenter asserts that FDA's Mobile Medical Applications Guidance (February 2015) suggests that licensed practitioners who develop devices solely for use in their professional practice and do not label or promote their product to be used generally by others would not be considered medical device manufacturers and therefore would not have to register, list, or submit a premarket application for their device.¹¹ The commenter concludes that JRC is not a device manufacturer because its GED devices are used only for its residents and are not promoted or offered for sale at other institutions, and argues JRC's GED devices are outside FDA's jurisdiction because they are not the subject of any interstate commercial sale.

(Response) FDA disagrees. The statute, regulation, and guidance cited by the commenter regarding registration, listing, and premarket review in no way impact FDA's authority to ban a device under section 516 of the FD&C Act, or our determinations regarding banning ESDs. FDA notes, however, that the GED

devices are subject to FDA jurisdiction and are subject to this ban.

(Comment 61) One comment argues a ban on ESDs for SIB or AB would discriminate against the most severely disabled and vulnerable members of the population, as well as their parents and guardians, by treating this subgroup differently from the larger disabled population as a whole by banning a treatment needed only by this subgroup, in violation of their right to equal protection of the laws under the Fourteenth Amendment of the Constitution.

(Response) FDA disagrees. The Equal Protection Clause of the Fourteenth Amendment prohibits States from denying citizens equal protection of the laws. As the commenter notes, citing *Tennessee v. Lane*, 541 U.S. 509 (2004), this generally requires similarly situated people to be treated alike, and classifications based on disability must have a rational relationship to a legitimate governmental purpose to pass Constitutional muster. FDA notes that although the Fourteenth Amendment applies to the States, the courts have applied the same Equal Protection analysis to the Federal government via the Fifth Amendment. See, e.g., *Buckley v. Valeo*, 424 U.S. 1, 93 (1976); *Weinberger v. Wiesenfeld*, 420 U.S. 636, 638 n.2 (1975). The Equal Protection analysis is not applicable to this ban. FDA is banning a particular device, defined in part by its intended use; FDA is not classifying individuals on the basis of any disabilities or applying its laws any differently to anyone on the basis of their disability or the severity of their disability. According to the commenter's logic, FDA would violate the Equal Protection Clause, for example, every time we approve a drug or device for a subpopulation of a larger patient population, or when we deny expansion of approval of a drug approved for a subpopulation to a larger patient population, which is clearly not so.

Finally, assuming for the sake of argument that Equal Protection analysis did apply, the commenter provides no analysis regarding how the ban would fail to bear a rational relationship to a legitimate governmental interest. Protecting patients from devices that present an unreasonable and substantial risk of illness or injury is a legitimate governmental interest. Because FDA has found this standard to be met specifically for ESDs for SIB or AB, as detailed in section III.A., application of the ban to this specific type of device, and not a broader or narrower category of devices, is clearly rationally related to this interest.

¹¹ FDA's guidance entitled "Mobile Medical Applications," issued February 9, 2015, has been superseded by "Policy for Device Software Functions and Mobile Medical Applications," issued September 27, 2019, available at <https://www.fda.gov/media/80958/download>.

(Comment 62) One commenter argues that the proposed ban would constitute a violation of the substantive due process rights of parents of students at JRC, arguing that parents have a fundamental right to choose ESD treatment for their children and that the ban is not narrowly tailored to serve a compelling government interest.

(Response) FDA disagrees. The ban is not a violation of parents' substantive due process rights because their interests do not constitute a fundamental right, and the ban is rationally related to a legitimate government interest.

The interest asserted by the commenter, parents' right to choose ESD treatment for their children, is not a fundamental right. The Supreme Court has recognized parents' fundamental right to direct the upbringing and education of their children. *Troxel v. Granville*, 530 U.S. 57 (2000). The Court has made clear, however, that there are limitations to such rights and that the State has "a wide range of power for limiting parental freedom and authority in things affecting the child's welfare." *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944). Under this rubric, the Court has upheld State interference with parental rights when there was a determination that the activity being restricted was harmful to a child's mental or physical health. See, e.g., *Jehovah's Witnesses v. King Cty. Hosp.*, 278 F. Supp. 488, 504 (W.D. Wash. 1967), *aff'd*, 390 U.S. 598 (1968) (*per curiam*) (holding that States may intervene when a parent refuses necessary medical care for a child).

Although the Supreme Court has not addressed the specific parental interests asserted here, several lower courts have addressed similar interests and have expressly stated that parents' fundamental rights do not encompass the right to choose for a child a particular type of health or medical treatment that the state has deemed harmful. See *Pickup v. Brown*, 740 F.3d 1208 (9th Cir. 2015); *Doe ex rel. Doe v. Governor of New Jersey*, 783 F.3d 150 (3d Cir. 2015).

The *Pickup* court was persuaded, in part, by the holdings of various courts that individuals do not have a fundamental right to choose specific health and medical treatments for themselves, noting that "it would be odd if parents had a substantive due process right to choose specific treatments for their children—treatments that reasonably have been deemed harmful by the state—but not for themselves." *Pickup*, 740 F.3d at 1236; see *Nat'l. Ass'n. for Advancement of Psychoanalysis v. Cal. Bd. of*

Psychology, 228 F.3d 1043, 1050 (9th Cir. 2000) ("substantive due process rights do not extend to the choice of type of treatment or of a particular health care provider"); *Mitchell v. Clayton*, 995 F.2d 772, 775 (7th Cir. 1993) ("a patient does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider if the government has reasonably prohibited that type of treatment or provider"); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (*per curiam*) (holding that there is no substantive due process right to obtain drugs that the FDA has not approved); *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) ("the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health."); see also *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (holding that terminally ill adult patients had no fundamental right to have access to investigational drugs that had not yet been approved by FDA for public use); *CaretoLive v. Eschenbach*, 525 F. Supp. 2d 952 (S.D. Ohio 2007) (holding that because an association of cancer patients did not have a "fundamental liberty interest" in a particular treatment, FDA's denial of the product's application did not violate the association's right to substantive due process).

Based on these cases, we disagree with the commenter that parents have a fundamental right to choose as a treatment for their children ESDs for SIB or AB devices that FDA has determined to present an unreasonable and substantial risk of illness or injury. Because the interests asserted are not fundamental rights, and a suspect class is not involved, the ban is not in violation of parents' substantive due process rights as long as it is rationally related to a legitimate State interest. See *Washington v. Glucksberg*, 521 U.S. 702, 728 (1997). As discussed above in the previous response, the ban is rationally related to FDA's legitimate interest in protecting patients from devices that present an unreasonable and substantial risk of illness or injury.

(Comment 63) One comment argues that the proposed ban would deprive the parents of students on whom ESDs are currently used at JRC of the procedural protections required by the Due Process Clause of the Fifth Amendment of the Constitution. This comment asserts that FDA's ban of ESDs for SIB or AB is an adjudicatory

decision against JRC, its students, and the parents of its students, and is inappropriately couched as a rulemaking because in substance and effect it is individual in impact and condemnatory in purpose. The comment argues that the affected parties are thus entitled to an oral evidentiary hearing to resolve the myriad factual disputes at issue with the benefit of procedural safeguards such as live cross-examination.

(Response) FDA disagrees. First, this ban of ESDs for SIB or AB is legislative, not adjudicative, in character and purpose, and as such, "it is not necessary that the full panoply of judicial procedures be used." *Hannah v. Larche*, 363 U.S. 420, 442 (1960). This ban plainly meets the definition of "rule" in the Administrative Procedure Act, 5 U.S.C. 551(4) that an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. There is a presumption of procedural validity for the rulemaking procedure prescribed in the APA, 5 U.S.C. 553, utilized here, as mandated by section 516 of the FD&C Act. See *American Airlines, Inc. v. C.A.B.*, 359 F.2d 624, 630 (D.C. Cir. 1966).

The only reason the commenter provides to support its argument that this ban is adjudicative is that "FDA repeatedly makes factual judgments and findings specifically concerning the medical care and treatment of a small subset of students at just one institution: JRC." To the extent the commenter is arguing that the facts and analysis underlying the ban only regard a subset of students at JRC, this is not true. As discussed throughout this final rule and the preamble to the proposed rule, the key analyses supporting this ban regard the risks and benefits posed by ESDs for SIB or AB and the state of the art of treatment for this patient population, which are based on evidence from the literature and other sources respecting patients and subjects treated and studied at many different institutions across the country over several decades. To the extent the commenter is arguing that banning ESDs for SIB or AB will only, as a practical matter, impact students at one institution, this does not render the ban adjudicatory, as explained in the following paragraphs.

An administrative law treatise cited in one of the cases relied upon by the commenter helps clarify the distinction between adjudicatory and legislative Agency action:

Adjudicative facts are the facts about the parties and their activities, businesses, and properties. Adjudicative facts usually answer the questions of who did what, where, when,

how, why, with what motive or intent; adjudicative facts are roughly the kind of facts that go to a jury in a jury case. Legislative facts do not usually concern the immediate parties but are general facts which help the tribunal decide questions of law and policy discretion.

Alaska Airlines, Inc. v. C.A.B., 545 F.2d 194, 201, n. 11 (D.C. Cir. 1976) (quoting 1 Davis, Administrative Law § 7.02 at 413 (1958)). The D.C. Circuit further illustrated the distinction with a passage from the Attorney General's Manual on the Administrative Procedure Act (1947) at 14–15:

The object of the rule making proceeding is the implementation or prescription of law or policy for the future, rather than the evaluation of a respondent's past conduct Conversely, adjudication is concerned with the determination of past and present rights and liabilities. Normally there is involved a decision as to whether past conduct was unlawful so that the proceeding is characterized by an accusatory flavor and may result in disciplinary action.

Id. at 201 n. 12.

Applying these considerations to this device ban, it is clear this is legislative and not adjudicatory action. The key facts relevant to FDA's ban of ESDs for SIB or AB do not concern who did what, where, when, how, why, with what motive or intent; rather, they concern the risks and benefits these devices present to the intended patient population, and the state of the art of medical treatment for this patient population across the United States. The purpose of the ban is to prospectively prohibit future manufacturing and sale of ESDs for SIB or AB by anyone anywhere in the United States. The purpose of this rulemaking proceeding is not to evaluate JRC's or any other entity's past conduct, nor is it to determine the lawfulness of any past conduct. Although some of the relevant data and information regard patients at JRC, they also regard patients and subjects treated and studied at a number of other institutions, reported in the literature over decades; these are general facts that have led FDA to determine that the legal standard for banning a device has been met. The proceeding is not punitive and may not result in disciplinary action (although future failure to comply with the ban may result in enforcement action).

In another case cited by the commenter, the Ninth Circuit described the primary considerations for distinguishing between legislation and adjudication as, “(1) whether the government action applies to specific individuals or to unnamed and unspecified persons; (2) whether the promulgating agency considers general

facts or adjudicates a particular set of disputed facts; and (3) whether the action determines policy issues or resolves specific disputes between particular parties.” *Gallo v. U.S. Dist. Ct. for the Dist. of Ariz.*, 349 F.3d 1169 (9th Cir. 2003) (citations omitted). Although this court pointed out that that the line between legislation and adjudication is not always easy to draw, it is easy to determine that this device ban falls well within the legislative side of the line.

First, it applies not only to JRC but to any entity that may wish to manufacture or sell ESDs for SIB or AB in the future. FDA notes that when we banned prosthetic hair fibers for concealing baldness, making it illegal for any entity to commercially distribute that product, there were no entities engaged in the commercial distribution of those products at the time of the ban (see 48 FR 25126, June 3, 1983).¹² FDA has cleared 510(k)s for other ESDs unrelated to JRC, although to FDA's knowledge none of these are currently in commercial distribution or use. The fact that only one entity happens to be holding ESDs for SIB or AB for sale does not render this an adjudicative action.

Second, in banning ESDs for SIB or AB, FDA has considered general facts regarding this device type and alternative treatments for this patient population from the literature and a wide variety of other sources, not a particular set of disputed facts regarding a particular party.

Third, the ban quite clearly determines general scientific and policy issues regarding whether ESDs for SIB or AB may be legally marketed in the United States, and does not resolve a dispute between particular parties, as did the cases cited by the commenter involving an adjudicative action (e.g., disputes regarding individuals' qualification for various types of government benefits or termination of their employment).

Further, FDA has provided the public, including affected entities and individuals, years of notice, as well as meaningful opportunities to participate in the process and present evidence and views regarding the ban. FDA first notified the public that it was considering a ban on ESDs for SIB or AB on March 14, 2014 (79 FR 17155). Although not required by statute, FDA then held the Panel Meeting to discuss issues relating to a potential ban of these devices. FDA opened a public docket for this meeting, received hundreds of written comments from a wide variety

of stakeholders, including JRC, JRC residents and their relatives, and provided an opportunity for verbal testimony, which was utilized by JRC, former JRC residents, and relatives of current and former JRC residents. FDA then issued a proposed rule to ban ESDs for SIB or AB on April 25, 2016, on which we received over 1,500 comments.

FDA has carefully considered and responded to these comments in this final rule. Contrary to the commenter's claims that FDA has not revealed all the sources upon which it has relied (an assertion for which the commenter provides no support), the extensive sources upon which FDA has relied in issuing this ban are listed in section XI of the proposed rule, 81 FR 24386 at 24414, and in section XI, and some, such as the reports FDA obtained from outside experts, were included in full in the public docket for the proposed rule. This process satisfies the requirements of due process.

The commenter argues that an evidentiary hearing with live cross-examination of witnesses is required to satisfy due process here. The cases cited by the commenter, e.g., *Goldberg v. Kelly*, 397 U.S. 254, 268–70 (1970) and *Gray Panthers v. Schweiker*, 652 F.2d 146, 167–72 (D.C. Cir. 1980), consider the due process right to an evidentiary hearing in adjudicative matters, and thus are not applicable to this legislative action. Further, in those cases, the courts held that due process requires an opportunity to be heard. Here, interested parties, including the individuals affected by this ban, on their own or through their representatives, have had ample opportunity to present evidence and their views to FDA, and FDA has clearly explained the reasons for banning ESDs for SIB or AB. Unlike the circumstances in *Gray Panthers*, FDA has no financial or other interest in the outcome of this proceeding other than the protection of the public health. This is not an area where cross-examination of people submitting comments would be warranted.

Indeed, this ban is much more akin to the cases cited by the commenter where the court found that live cross-examination was *not* required, for example, because the governmental proceeding was a general fact-finding investigation, not an adjudicatory proceeding, that would be unduly burdened by trial-like proceedings, *Hannah v. Larche*, at 451 (1960), or because the information critical to the decision, such as physicians' conclusions and other information from medical sources, is more effectively and efficiently communicated through

¹² Available at <https://www.govinfo.gov/content/pkg/FR-1983-06-03/pdf/FR-1983-06-03.pdf>.

written than oral presentation, *Mathews v. Eldridge*, 424 U.S. 319, 345 (1976). The same holds true here: key evidence underlying this ban is most effectively provided in written form, in particular the medical and scientific literature. FDA has already considered live testimony from over a dozen experts in the field and a wide variety of interested stakeholders with different views on the issues at its Panel Meeting, and little value would be added by a full or informal evidentiary hearing or live cross examination. Requiring such would place a huge burden on the Agency, with little, if any, benefit.

(Comment 64) One comment alleges FDA distorted comments submitted by the U.S. Department of Justice Civil Rights Division (DOJ) in the proposed rule, 81 FR 24386 at 24409, because FDA did not note that DOJ investigated JRC and took no enforcement action, which the commenter interprets to mean that JRC's program and use of ESDs fully complies with accepted professional judgment, practice, and standards. The commenter further asserts that FDA's reliance on DOJ's statements that ESDs do not conform to professional standards of care is misplaced and flawed, as DOJ conducted a full investigation and did not take enforcement action, and DOJ is not qualified to dictate healthcare practice.

(Response) FDA disagrees. There are many reasons why DOJ may have chosen not to take enforcement action against JRC under the statutes it administers, which are different from those administered by FDA. The fact that DOJ did not do so does not mean that JRC's use of ESDs complies with accepted professional judgment, practice, or standards. Indeed, as discussed in the proposed rule, DOJ clearly explained its position that ESDs for SIB or AB are harmful and have uncertain efficacy. As explained in the proposed rule, DOJ has experience in this field, because it must determine relevant standards of care in administering the statutes under its purview, and the evidence submitted by DOJ pertaining to the state of the art is corroborative of FDA's conclusions based on other evidence.

H. Transition Time

(Comment 65) Comments we received related to transitioning individuals on whom ESDs are currently used off of them supported making the transition time as short as possible after the ban is effective. One stated that if FDA allows a gradual transition, a definite end date must be set. However, one comment stated that improper transition would be

potentially life-threatening and likely to cause a return to behaviors and result in direct and immediate harm; any transition must happen under the care of a physician.

(Response) As explained in the proposed rule, this ban applies to future manufacture, sale, and distribution of devices as well as to devices already in commercial distribution and devices already sold to the ultimate user. For devices already in use, FDA agrees that transition off of ESDs should occur under the supervision of a physician and that the transition should end as soon as possible for the individual. The majority of comments suggested that use of ESDs can cease immediately and that an appropriate behavioral treatment plan can continue to address SIB or AB even without the device. As we noted in the proposed rule, the Massachusetts DDS and other providers have successfully transitioned several patients who were subject to ESDs at JRC to providers who do not use ESDs (81 FR 24386 at 24408 and 24411). We further note that JRC has implemented "a very comprehensive alternative behavior program" at its own facility that it described as "very successful" on occasions it decided its most powerful ESD was not effective, even for severe SIB. JRC's representative also said that its providers were able to transition individuals off of ESDs even though they had initially thought a transition "would be very unlikely" (see Ref. 15 at 148). However, in light of concerns about thorough assessments of the behaviors' functions and corresponding development of appropriate treatment plans, FDA recognizes that affected parties may need some period of time to establish or adjust treatment plans. We have determined the compliance date for residents already subject to the device with that in mind. In determining the amount of transition time for compliance, we relied upon clinical expert opinions, such as those provided by members of the Panel Meeting who opined that six months should be the maximum time allowed to transition (see Ref. 1).

VI. Effective Date and Compliance Dates

This rule is effective 30 days after its date of publication in the **Federal Register** (see **DATES**). We are establishing two compliance dates. For devices in use on specific individuals as of the date of publication and subject to a physician-directed transition plan, compliance is required 180 days after the date of publication of this rule in the **Federal Register** (see **DATES**). For all other devices, compliance is required 30

days after publication in the **Federal Register**. Section 501(g) of the FD&C Act provides that a device is adulterated if it is a banned device.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule would only affect one entity that is not classified as small, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Under this final rule we are banning ESDs for SIB or AB. Non-quantified benefits of the final rule include a reduction in adverse events, such as the risk of burns, PTSD, and other physical or psychological harms related to use of the device in this patient population.

We expect that the final rule will only affect one entity that currently uses these devices on residents of its facility. The final rule will impose costs on this entity to read and understand the rule,

13350

Federal Register / Vol. 85, No. 45 / Friday, March 6, 2020 / Rules and Regulations

as well as to provide affected individuals with alternative treatments. Although uncertain, other treatments or care at other facilities may cost more than the current treatment with the banned device.

To account for this uncertainty, we use a range of potential alternative treatment costs. At the lower bound, we assume that alternative treatments would cost the same as the current treatment. We use reimbursement data from the State of Massachusetts to estimate a potential upper bound for alternative treatments. The costs for the one affected entity to read and understand the rule range from around \$1,200 to \$5,200. The present value of the incremental treatment costs over 10

years ranges from \$0 to \$44 million, with a primary estimate of \$22 million at a 3 percent discount rate, and from \$0 to \$38 million, with a primary estimate of \$18.8 million at a 7 percent discount rate. Annualized costs range from \$0 million to \$5.0 million, with a primary estimate of \$2.5 million at a 3 percent discount rate, and from \$0 million to \$5.0 million, with a primary estimate of \$2.5 million at a 7 percent discount rate. The lower-bound cost estimates only include administrative costs to read and understand the rule with no incremental costs for alternative treatments. Additionally, there would be transfer payments between \$14 million and \$15 million annually either within the affected entity to treat the

same individuals using alternative treatments, or between entities if affected individuals transfer to alternate facilities for treatment. The final rule's costs and benefits are summarized in table 1.

We also examined the economic implications of the rule as required by the Regulatory Flexibility Act. The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule would only affect one entity that is not classified as small, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

TABLE 1—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Low estimate (million)	Primary estimate (million)	High estimate (million)	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits: Annualized. Monetized \$millions/year. Annualized. Quantified. Qualitative							Reduction in physical and psychological adverse events related to use of the device.
Costs: Annualized Monetized \$millions/year Annualized. Quantified. Qualitative	\$0.0 0.0	\$2.5 2.5	\$5.0 5.0	2018 2018	7 3	10 10	
Transfers: Federal. Annualized. Monetized \$millions/year Other Annualized Monetized \$millions/year	From: 13.8 13.8	14.2 14.2	14.6 14.6	To: 2018 2018	7 3	10 10	Transition costs to the affected entity and individuals for transitioning to alternative treatments.
	From: Affected entity for current treatment			To: Affected entity for other treatments or to other facilities that treat aggressive or self-injurious behavior			
Effects	State, Local or Tribal Government: State expenditures may rise or fall if individuals move across State boundaries. Small Business: No effect. Wages: No effect. Growth: No effect.						

In line with Executive Order 13771, in table 2 we estimate present and

annualized values of costs and cost savings over an infinite horizon. We do

not estimate any cost savings due to this final rule.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[In \$millions 2016 dollars, over infinite time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	\$36.7	\$0	\$73.4	\$82.5	\$0	\$165.0
Present Value of Cost Savings	\$0	0	0	0	0	0
Present Value of Net Costs	36.7	0	73.4	82.5	0	165.0
Annualized Costs	2.6	0	5.1	2.5	0	4.9

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE—Continued

[In \$millions 2016 dollars, over infinite time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Annualized Cost Savings	0	0	0	0	0	0
Annualized Net Costs	2.6	0	5.1	2.5	0	4.9

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 101) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VIII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this final rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused ESDs that will need to be handled after the effective date of the final rule.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste at municipal solid waste (MSW) facilities. The selected action will result in an initial batch disposal of ESDs primarily at a single geographic location, followed by a gradual, intermittent disposal of a small number of remaining devices where these devices are used. The total number of devices to be disposed is small, *i.e.*, estimated at fewer than 300 units. Overall, given the limited number of ESDs in commerce, the selected action is expected to have no significant impact on MSW and landfill facilities and the environment in affected communities.

The Agency has concluded that the final rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by

OMB under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

FDA has analyzed this rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain State requirements "different from or in addition to" certain Federal requirements applicable to devices (21 U.S.C. 360k; see *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). This rule creates a requirement under 21 U.S.C. 360k that bans ESDs for SIB or AB.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects

21 CFR Part 882

Medical devices, Neurological devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 882 and 895 are amended as follows:

PART 882—NEUROLOGICAL DEVICES

- 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Amend § 882.5235 by revising paragraph (b) to read as follows:

§ 882.5235 Aversive conditioning device.

* * * * *

(b) *Classification*. Class II (special controls), except for electrical stimulation devices for self-injurious or aggressive behavior. Electrical stimulation devices for self-injurious or aggressive behavior are banned. See § 895.105 of this chapter.

PART 895—BANNED DEVICES

- 3. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

- 4. Add § 895.105 to subpart B to read as follows:

§ 895.105 Electrical stimulation devices for self-injurious or aggressive behavior.

Electrical stimulation devices for self-injurious or aggressive behavior are aversive conditioning devices that apply a noxious electrical stimulus to a person's skin to reduce or cease self-injurious or aggressive behavior.

Dated: February 27, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

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